

Vaccines and Global Health: The Week in Review 8 December 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. 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 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.

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 <u>here</u> 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

Milestones :: Perspectives

::::::

<u>Industrial strategy delivers new vaccines manufacturing centre to lead the fight against deadly disease</u> [U.K.]

Ebola and Lassa fever are among the deadly diseases to be tackled in a pioneering new UK vaccine centre.

Press release 1 December 2018

- :: The UK's first-ever dedicated Vaccines Manufacturing Innovation Centre will ensure the UK life sciences industry remains at the forefront of worldwide efforts to tackle life-threatening diseases, including Ebola
 - :: The centre will be built in Oxford, creating more than 50 jobs in the local area
- :: Through the modern <u>Industrial Strategy</u>, the government is investing £66 million through UK Research and Innovation in the centre to help make Britain the best place in the world for innovators, including new treatments to help people live longer, healthier and happier lives through the Life Sciences Sector Deal
- :: Led by the Jenner Institute, a partnership between the University of Oxford and the Pirbright Institute, the new centre has been awarded funding by <u>UK Research and Innovation</u> of £66 million through the UK government's Industrial Strategy Challenge Fund (ISCF) Medicines Manufacturing challenge.
- \dots Additional funding of £10 million will come from commercial and other partners, including Janssen Vaccines & Prevention B.V. and Merck Sharp and Dohme. The centre will be further supported by expertise and training from GE Healthcare.

The core research teams will be drawn from academia and industry and will include significant new contributions from the London School of Hygiene & Tropical Medicine and Imperial College London as well as the University of Oxford. The programme will also benefit from access to technologies and intellectual property created by the partners.

::::::

Johnson & Johnson Announces Participation in New Collaboration Funded by the UK to Support Vaccines for Pandemic Preparedness

Janssen joins forces with UK government and multiple academic and industrial partners to support creation of Vaccine Manufacturing and Innovation Centre

New Brunswick, N.J., Dec. 3, 2018 – Johnson & Johnson today announced that Janssen Vaccines & Prevention B.V., part of its Janssen Pharmaceutical Companies, will participate in a new collaboration with the UK government and multiple partners from academia and industry that will result in the UK's first-ever dedicated Vaccine Manufacturing and Innovation Centre (VMIC).

UK Research and Innovation will invest £66 million in the centre as part of the Industrial Strategy Challenge Fund (ISCF) Medicines Manufacturing programme. VMIC will enable the

development and manufacture of vaccines for clinical trials and for emergency outbreak response and preparedness.

"Infectious diseases with pandemic potential need to be proactively addressed, in advance of outbreaks occurring, and developing new vaccines is a central part of any preparedness strategy," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "We applaud the UK's leadership in mobilizing partners from the across the public, private and academic sectors to tackle this challenge."

The VMIC is planned to be operational in Oxford by 2022, and will be a purpose-built facility capable of supporting multiple technologies, allowing for academic and industry collaboration on the development and manufacture of vaccines.

Three academic institutions will be engaged in VMIC: the Jenner Institute (a partnership between the University of Oxford and the Pirbright Institute), Imperial College, and the London School of Hygiene & Tropical Medicine. Additional funding of £10 million will come from commercial and other partners, including Janssen Vaccines & Prevention B.V. and Merck Sharp and Dohme (MSD), who will also share their extensive experience in the design and construction of such a facility, and in vaccine manufacturing and development. GE Healthcare will provide in-kind support on engineering and training.

"We are delighted to collaborate on this important initiative with the UK government and this impressive consortium of partners," said Johan Van Hoof, M.D., Global Therapeutic Area Head IDV, Vaccines, Janssen Pharmaceuticals R&D and Managing Director, Janssen Vaccines & Prevention B.V., who will be joining the governing board of VMIC. "Only by working in common cause can we achieve the goal of pandemic preparedness. If we take action now, working together, we can prevent the pandemics of the future. We are delighted to support this vital mission."

The VMIC is being launched to enable the rapid manufacture of vaccines in the event of an epidemic affecting the UK. It will also enable a rapid global response to emerging highly infectious pathogens. Additionally, VMIC aims to develop new technologies such as personalized cancer vaccines and vectors for gene therapy.

"Improving the development, production and application of new vaccines against infectious diseases requires expertise and collaboration across academia and industry," said UK Research and Innovation Chief Executive Professor Sir Mark Walport. "The Vaccine Manufacturing and Innovation Centre will play an important role in bringing expertise from industry and academia together to ensure we are prepared to respond to the threats of serious infections, including viruses with the potential to cause major national or global epidemics."

::::::

PREVENT Guidance

Developed by the Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies (PREVENT) Working Group, Johns Hopkins Berman Institute of Bioethics September 2018. :: 96 pages

PDF: http://vax.pregnancyethics.org/s/PREVENT-Web.pdf Overview

This Guidance provides a roadmap for the ethically responsible, socially just, and respectful inclusion of the interests of pregnant women in the development and deployment of vaccines against emerging pathogens. The Guidance is a product of the Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies (PREVENT) Working Group—a multidisciplinary, international team of 17 experts specializing in bioethics, maternal immunization, maternal-fetal medicine, obstetrics, pediatrics, philosophy, public health, and vaccine research and policy— in consultation with a variety of external experts and stakeholders.

The Guidance begins by setting forth an aspirational vision and makes the case for its moral importance. We then specify 22 concrete recommendations, organized around three key areas: public health preparedness, R&D, and vaccine delivery.

The recommendations are directed at a range of actors, including global and national policymakers, regional and national regulatory authorities, funders and sponsors, vaccine manufacturers, research institutions, trial networks and research groups, individual researchers, oversight bodies, ethics review committees, community advisory boards, and civil society organizations.

::::::

Cholera in Yemen: A Case Study of Epidemic Preparedness and Response

Johns Hopkins Center for Humanitarian Health

2018 :: 108 pages

PDF:

http://www.hopkinshumanitarianhealth.org/assets/documents/CHOLERA_YEMEN_REPORT_LON G Low Res Dec 4 2018.pdf

Overview

In 2015, the United Nations declared Yemen a Level 3 emergency. On September 28, 2016, a large-scale cholera outbreak began. Between April 27, 2017 and July 1, 2018, more than one million suspected cases in two waves were reported. In the last decade, several large-scale and high-mortality cholera outbreaks have occurred during complex humanitarian emergencies including in Iraq, Somalia, and South Sudan. While the issues of "what to do" to control cholera are largely known, context-specific practices on "how to do it" in order to surmount challenges to coordination, logistics, insecurity, access, and politics, remain needed. During the Yemen cholera outbreak response, questions arose on how to effectively respond to a cholera outbreak at a national scale during an existing emergency. The main objective of this report was to identify lessons learned from the preparedness and detection phase to the end of second wave of the cholera epidemic in Yemen to better prepare for future outbreaks in Yemen and similar contexts.

Excerpts from Executive Summary

...The use of the oral cholera vaccine (OCV) was slowed by the lack of cholera response planning and technical knowledge among the Ministry of Public Health and Population (MoPHP) and partners. The lack of an updated cholera preparedness and response plan meant that OCV was not integrated into the response mindset and thus, there was a lack of technical knowledge

and familiarly with OCV. OCV was not sufficiently discussed during the first wave, and was requested then rejected by the MoPHP during the second wave based on differing conceptions of the overall scale of distribution. The March 2018 plan is the first document that mentions an OCV strategy, based on a January 2018 risk assessment. The MoPHP then made a successful request to the Global Task Force for Cholera Control in April 2018 for 4.6 million doses for preventative use against future surges of cholera....

CONCLUSIONS:

The cholera response in Yemen was and remains extremely complicated and challenging for a variety of political, security, cultural, and environmental reasons. The study team recognizes these challenges and commends the government, international and national organizations, and the donors for working to find solutions in such a difficult context. There are no easy fixes to these challenges, and the conclusions and recommendations are meant to be constructive and practical, taking into account the extreme limitations of working in Yemen during an active conflict.

The findings were consistent across respondents and methods. The study team found that several areas gained strength throughout the second wave, including: an extensive operational footprint which reached into insecure areas; the strengthening of the collaborations between WHO and UNICEF and the health and WASH clusters; the initiation of a funding mechanism through the World Bank which enabled a timely response at scale; the revitalization of the WASH strategy; and, eventual consensus and use of OCV.

Conversely, the major gaps of this response are rooted in weaknesses in preparedness and the early strategies developed in the first wave. An after-action review after the first wave could have institutionalized these areas in order to prevent a much larger second wave.

The World Bank's commitment to the cholera response provides the rationale for major investment in bolstering the preparedness activities in Yemen and other conflict-affected contexts which would go far for addressing the foundational gaps discussed in this case study.

TOP 20 RECOMMENDATIONS FOR FUTURE PREPAREDNESS AND RESPONSE [Excerpt]

ORAL CHOLERA VACCINATION

- 18. Global recommendation: Different scenarios for OCV according to varying contexts should be integrated ahead of time into national cholera preparedness plans in general. This is especially important for "fragile" countries where there is a possibility of humanitarian emergencies developing or continuing.
- 19. Global and Yemen-specific recommendation: In complex and insecure environments like Yemen, smaller, geographically-targeted OCV campaigns should be anticipated and planned...

::::::

Ebola - Democratic Republic of the Congo

18: Situation report on the Ebola outbreak in North Kivu 5 December 2018 [Excerpts]

- ... Case Management
- :: Since the beginning of the response, 5 649 samples have been tested (including repeat samples).
- :: The ETCs continue to provide therapeutics under the MEURI protocol, in collaboration with the MoH and the Institut National de Recherche Biomédicale (INRB), together with supportive care measures. WHO is providing technical clinical expertise on-site and is assisting with the creation of a data safety management board.
- :: New patients continue to be treated in ETCs. As of 3 December 2018, 144 confirmed cases have recovered and been discharged. Bed occupancy was 63% in Beni ETC, 75% in Beni transit centre and 56% in Butembo ETC. All confirmed cases are being treated with a therapeutic under the MEURI framework after evaluation by clinical expert committee. All hospitalized patients receive food and psychological support.
- ...Implementation of ring vaccination protocol
- :: Vaccination continued on 3 December 2018 in Beni, Katwa, Butembo, Komanda, Vuhovi and Lubero, with 568 persons vaccinated, including 114 contacts, 175 contacts of contacts and 279 first line workers.
- :: As of 3 December 2018, the cumulative number of people vaccinated, is 39 845.

DONs <u>Ebola virus disease – Democratic Republic of the Congo</u> 6 December 2018 [Excerpt]

...Ebola virus disease in women and children

Concerns have been raised regarding the disproportionate number of women and children infected during this outbreak (Figure 3). To date, females accounted for 62% (280/450) of overall cases where sex was reported. Of all female cases, 83% (230/277) were aged ≥ 15 years. Of these women, at least 18 were pregnant, and an additional seven were breastfeeding or recently delivered at the time of infection. There have been 27 cases among infants less than one year of age, with 70% (19) of these being boys, and 21 fatalities (age-specific case fatality of 78%). There were also nine cases in infants aged less than one month. Children less than 15 years of age accounted for 24% (106/447) of cases.

There are likely a multitude of factors contributing towards this disproportionate disease burden observed in women and children. These include: exposure within formal and informal health facilities, involvement in traditional burial practices, transmission within family groups (including transmission between mothers caring for children), differences in health seeking behaviour, as well as the impact of ongoing conflict on the underlying population structure in affected areas. Among those with available information, commonly identified risk factors reported by cases include: having contact to a known case (224/320, 70%), having attended funerals (121/299, 40%) and having visited/admitted to a health facility before onset of EVD (46/139, 33%). Of note, 46% of female cases (84/181) reported having attended funerals, in contrast to 31% of male cases (37/118).

A concurrent increase in cases of malaria and the inadequate accompanying IPC in health settings are also likely to be contributory to the high rates of EVD among children. The recent conclusion of a four-day malaria control campaign in Beni on 2 December aimed at preventing further malaria deaths, as well as lessen the burden on health centres in order to address this potential source of transmission.

The MoH, WHO, are actively working with UNICEF and other partners to address the increased
risks observed in women (including pregnant or breastfeeding women) and young children, and
further strengthen measures to prevent and manage infections in these groups

::::::

Emergencies

POLIO

Public Health Emergency of International Concern (PHEIC)

Polio this week as of 04 December 2018 [GPEI]

- :: The circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak in Syria, which was first detected in 2017, has been successfully stopped. The announcement came at the heels of an official outbreak response assessment, comprising of experts in public health, epidemiology and virology, who reviewed evidence and concluded the outbreak was closed. Read the full statement here.
- :: On 27 November 2018, the 19th IHR Emergency Committee including members, advisers, and invited Member States convened to discuss the status of international spread of poliovirus. The Committee unanimously agreed that the risk of polio spread continues to be a Public Health Emergency of International Concern (PHEIC) and proposed an extension of Temporary Recommendations for an additional three months. The Committee expressed concern that complacency to achieving a polio-free world could now become the biggest risk to the effort and urged that all countries and partners regard polio eradication as an emergency. "We have the tools, we need to focus on what works, we need to get to every child," commented Prof. Helen Rees, Chairperson of the Committee. "The reality is that there is no reason why we should not be able to finish this job, but we have to keep at it." Prof. Rees and the Committee urged countries, donors and partners to continue their support, until a polio-free world is achieved, cautioning that failure to eradicate polio would lead to global resurgence of the disease, with potentially as many as 200,000 new cases occurring annually within ten years. "We have achieved eradication of a disease once before, with smallpox," Rees concluded. "The world is a much better place without smallpox. It's now more urgent than ever that we redouble our efforts and finish this job once and for all as well." The recommendations come amid the notification of the fourth cVDPV circulation in DRC, which underscores the need for sustained partnership, funding, and socio-political resolve. Read the full WHO statement including the Temporary Recommendations.
- :: The Africa Regional Commission for the Certification of poliomyelitis eradication (ARCC) was held in Nairobi, Kenya, from 12-16 November 2018. Made up of 16 health experts, recommendations were made to ten countries to address issues of disease surveillance gaps, inaccessibility and insecurity. Read the recommendations herc.

The Technical Advisory Groups (TAG) on Polio Eradication in Horn of Africa and Lake Chad Basin convened recently, to review the current status of polio outbreaks in both the regions and provide guidance on the next phase of the outbreak response.

::Featured on www.polioeradication.org: <u>Coffee with Polio Experts – Dr Mohammad Al Safadi</u>, Technical Officer for Polio Outbreak Preparedness and Response, talks about the tactics and strategies used to stop the Syria outbreaks of 2013, 2014, and the most recent outbreak of 2017, which was compounded by accessibility, security, and conflict issues.

:: Call for nomination of experts to serve on the Polio Research Committee to provide guidance to the Director of the Polio Department at WHO HQ on the research and development aspects in poliovirus eradication. Read the details <a href="https://example.com/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/heres/

The GPEI report to the upcoming WHO Executive Board (in January) has been published. The report provides a status update on polio eradication, summarizing programmatic, epidemiological and financial challenges to securing a lasting polio-free world, and introduces the concept of a new extended strategic plan to achieve global certification by 2023, taking into account the fact that circulation of wild poliovirus has not yet been interrupted. Read the report here.

Summary of new viruses this week:

Afghanistan – one wild poliovirus type 1 (WPV1) case and two positive WPV 1 environmental samples.

Pakistan – nine WPV1 positive environmental samples.

DRC – two cases of circulating vaccine-derived poliovirus type 2 (cVDPV2).

Nigeria – four cases of cVDPV2.

Somalia – one positive cVDPV2 environmental sample. See country sections below for more details.

::::::

<u>Djibouti carries out mass immunization to protect children against polio, amid outbreaks in the Horn of Africa</u>

5 December 2018 – Early analysis of campaign data points to a successful vaccination round in a polio-free country at risk of possible importation.

In the last week of October, Djibouti's Ministry of Health, working with WHO, UNICEF and other partners, successfully carried out the country's first polio National Immunization Days (NIDs) since 2015.

While Djibouti has not had a case of polio since 1999, the recent outbreak of polio in neighbouring countries in the Horn of Africa, and the low levels of routine immunization coverage in some areas in the country, are indications that Djibouti is still at risk if poliovirus spreads through population movements. Other countries in the Horn of Africa are already cooperating to control the existing outbreak and to reduce the risk of spread, and given that Djibouti is on a major migration route in the Horn of Africa, it makes a lot of sense for Djibouti to join this coordinated response...

::::::

<u>Countries of the Americas seek to strengthen measures to keep the Region free of polio and move towards global eradication</u> (12/05/2018)

PAHO convenes strategic partners and 140 public health professionals from 22 countries in the Region, in Guatemala this week. If polio is not eradicated there could be up 200,000 new cases worldwide each year within ten years.

::::::

Global Polio Eradication Initiative – Certification of poliovirus eradication November 2018 :: Statement

Global Commission for the Certification of Poliomyelitis Eradication (GCC) reviews criteria for certification

Attaining and sustaining a world free from all polioviruses

On 29-31 October 2018, the Global Commission for Certification of Poliomyelitis Eradication (GCC) met to review the criteria that will need to be met to achieve global certification of wild poliovirus (WPV) eradication.

As the world approaches successful eradication of WPV transmission, the GCC's work takes on urgency, including consideration of circulating vaccine-derived polioviruses (cVDPVs). While these are not a new phenomenon, they become more significant, as does the need for effective containment of all polioviruses in laboratories and vaccine manufacturing facilities. The GCC has recommended a process of sequential certification of WPV eradication and confirmation of the absence of VDPVs, when the data become available. The Director General has accepted the GCC recommendation for sequential certification.

While the operational and programmatic aspects of achieving and sustaining a world free of all polioviruses – be they wild or vaccine-derived – have been well-established, the GCC is focusing its discussions on the necessary verification processes associated with this eventual achievement. Following the certification that WPV transmission has been stopped – and after OPV has been withdrawn – the absence of VDPVs will also need to be validated.

The assessment that all WPV transmission has been interrupted globally is the critical step which will mark the launch of preparations for cessation of all oral polio vaccine (OPV) use. Inadequate routine immunization levels coupled with subnational gaps in surveillance in high-risk countries continue to be the main risk factors for the emergence or continuation of cVDPVs. Both risk factors must be addressed. However, the only and surest way to prevent cVDPVs in the future is to rapidly stop OPV use, which can only occur after the successful eradication of WPVs. As such, the polio eradication program now has two urgent tasks – to eradicate WPVs as quickly as possible and to stop the use of OPV globally.

With no wild poliovirus type 3 (WPV3) reported globally since November 2012 (from Nigeria), the GCC concluded that the world could be ready to certify the eradication of WPV3, and urged the GPEI and Member States to ensure that full documentation is available to achieve this goal. This type-specific global certification would ideally follow a similar process as that used for the certification of WPV2 eradication in 2015. The GCC recommended that the GPEI conduct a comprehensive review of the implications of such sequential certification, and report back to it in 2019.

The GCC also continues to evaluate evidence that polioviruses will be rigorously contained where they are being held (in a limited number of research or diagnostics laboratories, and in

vaccine manufacturing facilities). The Containment Advisory Group and the Containment Working Group guide the operationalization of this work, through implementation of the WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII).

The WHO Director-General has accepted the outcomes and recommendations of the GCC and these will be incorporated into a global strategy for eradication covering the period 2019-2023 (currently being developed in a broad consultative process, and to be presented to the World Health Assembly in May 2019). The full report from the GCC's meeting will subsequently be made available upon publication at www.polioeradication.org.

The GCC's work and efforts will assure the independent verification that transmission of all polioviruses has been interrupted globally, and that all necessary safeguards to sustain a poliofree world have been put in place.

Additional background:

The GCC is independent of WHO and of involvement in national polio vaccination implementation or polio surveillance programmes. WHO Regions are eligible for certification following the absence of WPV from any country in that region from any population source in the presence of certification-standard surveillance. Regional certification is conducted by Regional Certification Commissions (RCCs). Global certification will follow the successful certification of all six WHO regions, and will be conducted by the GCC.

As at 2018, four regions have been certified as free of WPVs: Region of the Americas (1994), the Western Pacific Region (2000), the European Region (2002), and the South-East Asia Region (2014).

For more information, please see:

http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/certification/ http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/

::::::

Editor's Note:

WHO has posted a <u>refreshed emergencies page</u> which presents an updated listing of Grade 3,2,1 emergencies as below.

WHO Grade 3 Emergencies [to 8 Dec 2018]

<u>Democratic Republic of the Congo</u>

- :: 18: Situation report on the Ebola outbreak in North Kivu 5 December 2018
- :: DONs <u>Ebola virus disease Democratic Republic of the Congo</u> 6 December 2018 [See Milestones above for more detail]

Bangladesh - Rohingya crisis

:: Weekly Situation Report 53 -30 November 2018 [Excerpt]
HEALTH OPERATIONS
OCV Campaign:

After completion of 2nd week of OCV campaign, 163,441 (101.5%.) received the vaccination. Among them 119,649 (107.3%) were FDMN beneficiaries and 43,792 (88.5%) from host community. Out of total target of 328, 556, 49.7% vaccination completed. Among them 53.2% were FDMN beneficiaries and 42.3% from host community. Besides the major portion of the FDMN and HC: Registered camps, No-man's land and people engaged in different activities adjacent to camps are being covered.

Rapid Convenience monitoring through house to house:

In total 2116 beneficiaries were interviewed till 28 November 2018. Evaluated coverage was 92.5%. The main reasons not being vaccinated were beneficiaries not at home (32%), not aware of campaign (23%) and beneficiaries too busy (14%). The main means of mobilization were majhee and FDMN mobilizers (46.2), megaphone (30.1) and moni flag (17.5)...

Syrian Arab Republic

:: WHO update on reported chemical event in Aleppo, Syria 29 November 2018

Myanmar - No new announcements identified
Nigeria - No new announcements identified
Somalia - No new announcements identified
South Sudan - No new announcements identified
Yemen - No new announcements identified

::::::

WHO Grade 2 Emergencies [to 8 Dec 2018]

<u>Sudan</u>

:: WHO Member States sign Khartoum Declaration on Sudan and Bordering Countries: Cross-Border Health Security

4 December 2018 – Six countries in WHO's Eastern Mediterranean and African Regions have signed a declaration committing themselves to strengthening preparedness and response to public health threats and events across borders in an effort to further the implementation of the International Health Regulations (IHR 2005) and enhance global health security. The Khartoum Declaration on Sudan and Bordering Countries: Cross-Border Health Security was signed by Chad, Egypt, Ethiopia, Libya, South Sudan and Sudan on 22 November 2018 in Khartoum, Sudan...

Brazil (in Portugese) - No new announcements identified

Cameroon - No new announcements identified

Central African Republic - No new announcements identified

Ethiopia - No new announcements identified

Hurricane Irma and Maria in the Caribbean - No new announcements identified

Iraq - No new announcements identified

occupied Palestinian territory - No new announcements identified

Libya - No new announcements identified

MERS-CoV - No new announcements identified

Niger - No new announcements identified

Sao Tome and Principe Necrotizing Cellulitis (2017) - No new announcements identified

Ukraine - No new announcements identified

<u>Zimbabwe</u> - No new announcements identified

WHO-AFRO: Outbreaks and Emergencies Bulletin, Week 48: 24-30 November 2018

The WHO Health Emergencies Programme is currently monitoring 57 events in the region. This week's edition covers key ongoing events, including:

- :: Yellow fever in South Sudan
- :: Ebola virus disease in the Democratic Republic of the Congo
- :: Cholera in Zimbabwe
- :: Hepatitis E in Central African Republic
- :: Humanitarian crisis in Ethiopia.

::::::

WHO Grade 1 Emergencies [to 8 Dec 2018]

Afghanistan

Chad

Indonesia - Sulawesi earthquake 2018

Kenya

Lao People's Democratic Republic

Mali

Namibia - viral hepatitis

Peru

Philippines - Tyhpoon Mangkhut

Tanzania

::::::

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.

Yemen

:: <u>Yemen: Al Hudaydah Update Situation Report No. 15, Reporting period: 14 November - 2</u> December 2018

Syrian Arab Republic - No new announcements identified.

::::::

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

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

Ethiopia - No new announcements identified.

Somalia - No new announcements identified.

::::::

"Other Emergencies"

<u>Indonesia: Central Sulawesi Earthquake</u> – No new announcements identified.

::::::

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 8 Dec 2018]

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

- :: 18: Situation report on the Ebola outbreak in North Kivu 5 December 2018
- :: DONs <u>Ebola virus disease Democratic Republic of the Congo</u> 6 December 2018 [See Milestones above for more detail]

MERS-CoV [to 8 Dec 2018]

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

- No new announcements identified.

Yellow Fever [to 8 Dec 2018]

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

- No new announcements identified.

Zika virus [to 8 Dec 2018]

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

- No new announcements identified.

::::::

WHO & Regional Offices [to 8 Dec 2018]

7 December 2018

News Release

New WHO report highlights insufficient progress to tackle lack of safety on the world's roads

5 December 2018 News Release

Health benefits far outweigh the costs of meeting climate change goals

3 December 2018

Statement

WHO statement for COP24

::::::

Weekly Epidemiological Record, 7 December 2018, vol. 93, 49 (pp. 661–680)

:: Meeting of the Strategic Advisory Group of Experts on Immunization, October 2018 – Conclusions and recommendations

::::::

GIN November 2018 pdf, 1.22Mb 3 December 2018

::::::

WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO

Selected Featured News

- :: Ethiopia launches Human Papillomavirus Vaccine for 14 year old girls 06 December 2018
- :: Niger vaccinates 152,000 people against cholera in high-risk areas 06 December 2018
- :: <u>African countries test their capacity to respond to a deadly global flu pandemic</u> 04 December 2018
- :: <u>Uganda and DRC bordering districts agree to intensify cross-border surveillance to tackle</u> Ebola 03 December 2018
- :: <u>Tackling cholera outbreaks in North-east humanitarian emergencies</u> 03 December 2018

WHO Region of the Americas PAHO

:: Countries of the Americas seek to strengthen measures to keep the Region free of polio and move towards global eradication (12/05/2018)

PAHO convenes strategic partners and 140 public health professionals from 22 countries in the Region, in Guatemala this week. If polio is not eradicated there could be up 200,000 new cases worldwide each year within ten years.

WHO South-East Asia Region SEARO

- No new announcement identified

WHO European Region EURO

- :: Health is a human right 07-12-2018
- :: Preventing hospital-acquired infections in eastern Ukraine saves lives 06-12-2018
- :: <u>Interparliamentary Assembly of Member Nations of the Commonwealth of Independent</u> States supports international measures to stop illicit tobacco trade 04-12-2018

WHO Eastern Mediterranean Region EMRO

- :: Initiating hepatitis C treatment in Afghanistan 5 December 2018
- :: <u>Djibouti carries out mass immunization to protect children against polio</u> 5 December 2018

WHO Western Pacific Region

- No new announcement identified

::::::

CDC/ACIP [to 8 Dec 2018]

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

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

MMWR News Synopsis for Friday, December 7, 2018

<u>Public Health Response to an Avian Influenza H7N8 Outbreak in Commercial Turkey Flocks—Indiana, 2016</u>

Surveillance for influenza among responders to an outbreak of avian influenza in turkeys in Indiana in 2016 did not detect any human illnesses. Highly pathogenic avian influenza outbreaks are animal health emergencies that require aggressive control measures. If the virus causing an outbreak is capable of causing human illness, then there could be health risks for the responders. The Indiana State Department of Health and the Dubois County Health Department worked together to monitor the health of people who responded to an outbreak of avian influenza in commercial turkey flocks in 2016. No human cases of avian influenza were detected.

::::::

Africa CDC [to 8 Dec 2018] https://au.int/en/africacdc

No new digest content identified.

::::::

China CDC

http://www.chinacdc.cn/en/

New website launched...no "news" or "announcements" page identified.

National Health Commission of the People's Republic of China

http://en.nhfpc.gov.cn/ Selected Updates/ Press Releases/ Notices No new digest content identified.

::::::

Announcements

BMGF - Gates Foundation [to 8 Dec 2018]

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

Bill & Melinda Gates Medical Research Institute [to 8 Dec 2018]

https://www.gatesmri.org/

The Bill & Melinda Gates Medical Research Institute is a non-profit biotech organization. Our mission is to develop products to fight malaria, tuberculosis, and diarrheal diseases—three major causes of mortality, poverty, and inequality in developing countries. The world has

unprecedented scientific tools at its disposal; now is the time to use them to save the lives of the world's poorest people

No new digest content identified.

CARB-X [to 8 Dec 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. No new digest content identified.

CEPI – Coalition for Epidemic Preparedness Innovations [to 8 Dec 2018]

http://cepi.net/

Press releases

Canadian PM, Justin Trudeau, reaffirms commitment to CEPI at the G20

Posted on 02ND DEC 2018 by Mario Christodoulou

In support of the G20 efforts on global health, Canadian Prime Minister, Justin Trudeau, announced an additional CAD10 million contribution to the Coalition for Epidemic Preparedness Innovations (CEPI), which will help us develop new life-saving vaccines to combat emerging infectious diseases...

EDCTP [to 8 Dec 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 Latest news

No new digest content identified.

Emory Vaccine Center [to 8 Dec 2018]

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

European Medicines Agency [to 8 Dec 2018]

http://www.ema.europa.eu/ema/News and press releasesNo new digest content identified.

European Vaccine Initiative [to 8 Dec 2018]

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

05 December 2018

TDR Clinical Research & Development Fellowships

Deadline for submission: 7 March 2019, 16:00 (GMT)

FDA [to 8 Dec 2018]

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm No new digest content identified.

December 06, 2018 -

Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's new strategic framework to advance use of real-world evidence to support development of drugs and biologics

December 04, 2018 -

FDA takes new action to advance the development of reliable and beneficial genetic tests that can improve patient care

Fondation Merieux [to 8 Dec 2018]

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

Partner event

ASLM 2018 – Preventing and controlling the next pandemic: the role of laboratory

December 10 - 13, 2018 - Abuja (Nigeria)

Mérieux Foundation co-organized event

<u>Dengue pre-vaccination screening based on serostatus: rapid tests and implementation strategies</u>

January 14 - 16, 2019 - Les Pensières Center for Global Helath, Veyrier du Lac (France)

Gavi [to 8 Dec 2018] https://www.gavi.org/ 05 December 2018

Harnessing the power of partnerships to benefit maternal, newborn & child health

The Partners Forum for The Partnership for Maternal, Newborn & Child Health represents a landmark opportunity to push for action to improve the health and well-being of women, children and adolescents

New Delhi, India, 5 December - Gavi's Deputy CEO, Anuradha Gupta, will join over 1,200 representatives from governments, civil society and the private sector at a high-level meeting in New Delhi (12–13 December) to demonstrate the power of partnerships to improve and transform the lives of women, children and adolescents.

Hosted by the Government of India, the <u>Partners' Forum of The Partnership for Maternal</u>, <u>Newborn & Child Health (PMNCH)</u> will set out to align objectives, strategies and resources, as well as seeking agreement on interventions to improve maternal, newborn, child and adolescent health...

Mobile phones and digital technology to boost vaccine delivery in Uganda

New collaboration will address vaccine supply challenges in 171 health facilities ensuring that children in the hardest-to-reach areas are protected with vaccines.

Geneva, 4 December 2018 – Thousands of children living in the densely populated districts of Wakiso, Nakaseke and Nakasongola in central Uganda will get better access to life-saving vaccines thanks to a new collaboration between the Uganda Ministry of Health, Gavi, the Vaccine Alliance, UPS and Freight in Time Ltd (FIT). The 18 month pilot project will use a customised mobile app and a wireless temperature monitoring system to help address supply chain challenges in 171 health facilities in three districts with the some of the lowest immunisation coverage and the highest number of unimmunised children in the country...

GHIT Fund [to 8 Dec 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 8 Dec 2018]

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

02 December 2018

At Mandela 100, Global Fund Builds on South Africa's Progress against HIV

The Global Fund to Fight AIDS, Tuberculosis and Malaria strengthened its partnership with South Africa in the fight against HIV, announcing a new grant aimed at capitalizing on strong HIV programs to make even greater progress in treatment and prevention, in protecting and promoting human rights, and in strengthening health systems.

The grant, for US\$369 million, includes specific efforts aimed at lowering HIV infection rates among adolescent girls and young women who are disproportionately affected by the disease...

Hilleman Laboratories [to 8 Dec 2018]

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

Human Vaccines Project [to 8 Dec 2018]

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

IAVI [to 8 Dec 2018] https://www.iavi.org/newsroom No new digest content identified.

IFFIm

http://www.iffim.org/library/news/press-releases/ No new digest content identified. **IVAC** [to 8 Dec 2018]

https://www.jhsph.edu/research/centers-and-institutes/ivac/index.html *No new digest content identified.*

IVI [to 8 Dec 2018] http://www.ivi.int/ IVI News & Announcements No new digest content identified.

JEE Alliance [to 8 Dec 2018] https://www.jeealliance.org/
No new digest content identified.

MSF/Médecins Sans Frontières [to 8 Dec 2018]

http://www.msf.org/

Selected News; Project Updates, Reports

Pakistan

Bringing hope to sufferers of a neglected disease

Project Update 5 Dec 2018

In May, MSF opened a treatment centre for cutaneous leishmaniasis in Peshawar - its fourth in Pakistan.

Hepatitis C

Appeal lodged against decision to uphold Gilead's patent on hepatitis C drug Press Release 5 Dec 2018

Paris – Six organisations, including Médecins Sans Frontières (MSF), have just appealed the European Patent Office's September decision to uphold US pharmaceutical corporation Gilead Science's patent on the key hepatitis C drug sofosbuvir.

The appeal – filed by Médecins du Monde (MdM), MSF, AIDES (France), Access to Medicines Ireland, Praksis (Greece) and Salud por Derecho (Spain) – states that the European Patent Office (EPO) should revoke Gilead's patent because it does not meet the requirements to be a patentable invention from a legal or scientific perspective.

Democratic Republic of Congo

Ebola spreads further into urban communities and isolated areas in North Kivu Project Update 3 Dec 2018

The Ebola epidemic continues to spread through the Democratic Republic of Congo (DRC)'s North Kivu province. The newest areas to be affected include the city of Butembo and a number of isolated areas that are hard to reach. So far, 440 people have been infected with the virus, 255 of whom have died. Our teams continue to strengthen their efforts to help bring the epidemic under control.

NIH [to 8 Dec 2018]

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

December 4, 2018

NIH researcher presents encouraging results for gene therapy for severe sickle cell

— This study is part of decades of research on sickle cell disease that have opened the door to novel genetic approaches to curative therapies.

A scientist from the National Institutes of Health will present promising, early results from a human clinical trial testing a novel gene replacement therapy in people with severe sickle cell disease. Preliminary findings suggest that the approach has an acceptable level of safety and might help patients consistently produce normal red blood cells instead of the sickle-shaped ones that mark this painful, life-threatening disease.

The experimental treatment involves removing hematopoietic stem cells from the patients' bone marrow or blood and adding a therapeutic beta globin gene, which is defective in people with sickle cell disease. The cells are then returned to the patients, leading to the production of anti-sickling hemoglobin (T87Q).

Current data from the ongoing HGB-206 Phase 1 multicenter nationwide study will be presented at the 60th Annual Meeting of the American Society of Hematology (ASH), Dec. 1-4, in San Diego...

PATH [to 8 Dec 2018] https://www.path.org/media-center/ No new digest content identified.

Sabin Vaccine Institute [to 8 Dec 2018] http://www.sabin.org/updates/pressreleases

No new digest content identified.

UNAIDS [to 8 Dec 2018] http://www.unaids.org/en Selected Press Releases/Reports/Statements 4 December 2018

South Africa launches campaign to expand access to HIV treatment

On World AIDS Day, South Africa launched a multidisease national wellness campaign to accelerate screening and testing for HIV, tuberculosis, sexually transmitted infections and noncommunicable diseases, including hypertension and diabetes. The campaign, known as Cheka Impilo, is a direct response to the call by the President of South Africa, Cyril Ramaphosa, during his first State of the Nation address in February 2018 to initiate an additional 2 million people on HIV treatment by 2020, find 88 000 missing tuberculosis cases annually and screen 7 million people for noncommunicable diseases in the first year...

UNICEF [to 8 Dec 2018] https://www.unicef.org/media/press-releases Selected Press Releases/Reports/Statements Statement

Humanitarian assistance continues to prevent a massive human catastrophe in Yemen but it is not enough

UN agencies warn that an urgent scale up of humanitarian assistance is needed to save lives 07/12/2018

Press release

Refugee and migrant children and youth report severe deprivations while on the move — UNICEF

UNICEF releases alarming data from poll of nearly 4,000 refugee and migrant children and youth ahead of Global Compact for Migration Summit in Marrakech 07/12/2018

Vaccine Confidence Project [to 8 Dec 2018]

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

Vaccine Education Center – Children's Hospital of Philadelphia [to 8 Dec 2018]

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

Wellcome Trust [to 8 Dec 2018]

https://wellcome.ac.uk/news Opinion | 6 December 2018

Social science research: a much-needed tool for epidemic control

João Rangel de Almeida

Portfolio Development Manager Wellcome

To control epidemics, it's essential to understand the contexts where they take place. Social researchers are helping to uncover ethical and practical challenges that are critical to the people caught in the middle of an outbreak.

Explainer | 5 December 2018

Research saves lives in epidemics like Ebola

Protecting the people of the Democratic Republic of the Congo from Ebola takes a chain of responders from all over the world. With one outbreak earlier this year over, and a second ongoing, research has been at the heart of the response.

Q&A | 4 December 2018

What are human infection studies and why do we need them?

Human infection studies have the power to rapidly accelerate the development of muchneeded vaccines and treatments. In this Q&A, we explain what they are, how they work and why they are important.

News | 3 December 2018

Second global call to action against drug-resistant infections

Wellcome has co-hosted a second global event, in Ghana, to help drive pioneering action to stop the rise and spread of superbugs.

The Wistar Institute [to 8 Dec 2018]

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

No new digest content identified.

World Organisation for Animal Health (OIE) [to 8 Dec 2018]

http://www.oie.int/en/for-the-media/press-releases/2018/ No new digest content identified.

::::::

BIO [to 8 Dec 2018]

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

No new digest content identified.

DCVMN – Developing Country Vaccine Manufacturers Network [to 8 Dec 2018]

http://www.dcvmn.org/

No new digest content identified.

IFPMA [to 8 Dec 2018]

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

05 December 2018

R&D biopharmaceutical industry revamp ethical code to apply as base line of industry behavior worldwide

- : New R&D biopharmaceutical industry Code of Practice comes into effect on 1 January 2019.
- :: Changes reflect increasingly complex dilemmas faced by R&D biopharmaceutical industry professionals which call just as much for rules, as for strong ethical values that can build a culture of trust.
- :: New Code of Practice aims to improve guidance to IFPMA members on how to conduct business when interacting with the healthcare community worldwide.

04 December 2018

<u>David A. Ricks Elected New President of the International Federation of Pharmaceutical Manufacturers & Associations</u>

- :: David A. Ricks, Chairman and Chief Executive Officer, Eli Lilly and Company, takes over as President of IFPMA from Ian C. Read, Chairman of the Board and Chief Executive Officer, Pfizer.
- :: New President to highlight the need for forward-looking policies that encourage innovation, as well as strengthened health systems in order to sustain the last-half century's hard-won global health gains.
- :: The outgoing President leaves a legacy of biopharmaceutical collaborative firsts: Access Accelerated, Pat-INFORMED and AMR Industry Alliance.

PhRMA [to 8 Dec 2018] http://www.phrma.org/press-room *No new digest content identified.*

* * * *

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

December 2018 Volume 46, Issue 12, p1319-1424, e75-e90 http://www.ajicjournal.org/current [Reviewed earlier]

American Journal of Preventive Medicine

December 2018 Volume 55, Issue 6, p759-944 http://www.ajpmonline.org/current [Reviewed earlier]

American Journal of Public Health

December 2018 108(12) http://ajph.aphapublications.org/toc/ajph/current [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 99, Issue 6, 2018 http://www.ajtmh.org/content/journals/14761645/99/6 Articles

Do Incarcerated Populations Serve as a Reservoir for Tuberculosis in South Africa?

Alana Sharp, J. Travis Donahoe, Amanda Milliken, Jacqueline Barocio, Salome Charalambous and Zoë M. McLaren https://doi.org/10.4269/ajtmh.17-0652

Annals of Internal Medicine

4 December 2018 Vol: 169, Issue 11

http://annals.org/aim/issue

Original Research

<u>Long-Term Protection After Fractional-Dose Yellow Fever Vaccination: Follow-up Study of a Randomized, Controlled, Noninferiority Trial</u>

Anna H.E. Roukens, MD, PhD *; Karlijn van Halem, MD *; Adriëtte W. de Visser, BSc; Leo G. Visser, MD, PhD

Abstract

Background:

Outbreaks of yellow fever and a frequently depleted vaccine stock increase demand for a dose-sparing strategy. A fractional dose of 17D yellow fever virus (17D-YFV) vaccine has been shown to be noninferior to the standard dose in inducing seroprotection.

Objective:

To evaluate whether fractional-dose vaccination can confer long-term immunity.

Design:

10-year follow-up of a subgroup of a randomized, controlled, noninferiority trial. (Dutch Trial Register: NTR7094 [current study] and ISRCTN46326316 [original study]) Setting:

The Netherlands.

Participants:

Seventy-five of 155 participants in the original trial provided a blood sample for this study. These 75 participants had received primary vaccination with 17D-YFV vaccine 10 years before. Forty received a 0.1-mL fractional dose intradermally, and 35 received the standard 0.5-mL dose subcutaneously.

Measurements:

Virus-neutralizing antibody responses were measured by a plaque reduction neutralization test. Results:

Thirty-nine of 40 (98% [95% CI, 89% to 100%]) participants had protective levels of yellow fever—neutralizing antibodies more than 10 years after receiving a fractional dose of 17D-YFV vaccine compared with 34 of 35 (97% [CI, 87% to 100%]) in the standard-dose group. Limitation:

Only 48% of participants from the original trial participated in this study.

Conclusion:

Intradermal administration of a one-fifth dose of yellow fever vaccine induced a protective immune response that lasted for 10 years after vaccination. Persons receiving a fractional dose of yellow fever vaccine do not require a booster vaccination for long-term protection against yellow fever.

Primary Funding Source:

Leiden University Medical Center and the International Society of Travel Medicine.

BMC Cost Effectiveness and Resource Allocation

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

(Accessed 8 Dec 2018)

[No new digest content identified]

BMJ Global Health

December 2018 - Volume 3 - 6 https://gh.bmj.com/content/3/6 [Reviewed earlier]

BMC Health Services Research

http://www.biomedcentral.com/bmchealthservres/content (Accessed 8 Dec 2018) Research article

How to assure access of essential RMNCH medicines by looking at policy and systems factors: an analysis of countdown to 2015 countries

In 2000, the Millennium Development Goals set targets for social achievements by 2015 including goals related to maternal and child health, with mixed success. Several initiatives supported these goals includi...

Authors: Jane Briggs, Martha Embrey, Blerta Maliqi, Lisa Hedman and Jennifer Requejo

Citation: BMC Health Services Research 2018 18:952

Published on: 7 December 2018

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 8 Dec 2018) Research article

Immunogenicity and safety of a tetanus-diphtheria vaccine and a 13-valent pneumococcal conjugate vaccine after concomitant vaccination in ≥ 50-year-old adults

When two or more vaccines are administered concurrently, there is concern about safety and immunogenicity from vaccine interaction.

Authors: Joon Young Song, Hee Jin Cheong, Ji Yun Noh, Min Joo Choi, Jin Gu Yoon, Saem Na Lee, Seong Hui Kang, Eun Joo Jeong, Yu Mi Jo and Woo Joo Kim

Citation: BMC Infectious Diseases 2018 18:628

Published on: 5 December 2018

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content (Accessed 8 Dec 2018) Debate

| 6 December 2018

Exploring the ethics of global health research priority-setting

Thus far, little work in bioethics has specifically focused on global health research priority-setting. Yet features of global health research priority-setting raise ethical considerations and concerns related to health justice. For example, such processes are often exclusively disease-driven, meaning they rely heavily on burden of disease considerations. They, therefore, tend to undervalue non-biomedical research topics, which have been identified as essential to helping reduce health disparities. In recognition of these ethical concerns and the limited scholarship and dialogue addressing them, we convened an international workshop in September 2015. The

workshop aimed to initiate discussion on the appropriate relationship between global and national levels of health research priority-setting and to begin exploring what might be ethically required for priority-setting at each of those levels.

Authors: Bridget Pratt, Mark Sheehan, Nicola Barsdorf and Adnan A. Hyder

BMC Medicine

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

(Accessed 8 Dec 2018)

Research article

<u>Cost-effectiveness of vaccination of immunocompetent older adults against herpes</u> <u>zoster in the Netherlands: a comparison between the adjuvanted subunit and live-attenuated vaccines</u>

The newly registered adjuvanted herpes zoster subunit vaccine (HZ/su) has a higher efficacy than the available live-attenuated vaccine (ZVL). National decision-makers soon need to decide whether to introduce H...

Authors: Pieter T. de Boer, Alies van Lier, Hester de Melker, Albert J. M. van Wijck, Jan C.

Wilschut, Albert Jan van Hoek and Maarten J. Postma

Citation: BMC Medicine 2018 16:228 Published on: 6 December 2018

BMC Pregnancy and Childbirth

http://www.biomedcentral.com/bmcpregnancychildbirth/content (Accessed 8 Dec 2018)

[No new digest content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles

(Accessed 8 Dec 2018)

Research article

<u>Vaccination in England: a review of why business as usual is not enough to maintain coverage</u>

The vaccine system in England underwent radical changes in 2013 following the implementation of the Health and Social Care Act. There have since been multi-year decreases in coverage of many vaccines. Healthca...

Authors: Tim Crocker-Buque and Sandra Mounier-Jack

Citation: BMC Public Health 2018 18:1351

Published on: 6 December 2018

Debate

The cholera outbreak in Yemen: lessons learned and way forward

The Yemen cholera outbreak has been driven by years of conflict and has now become the largest in epidemiologically recorded history with more than 1.2 million cases since the beginning of the outbreak in Apri...

Authors: Frederik Federspiel and Mohammad Ali

Citation: BMC Public Health 2018 18:1338

Published on: 4 December 2018

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 8 Dec 2018) [No new digest content identified]

BMJ Open

December 2018 - Volume 8 - 12 http://bmjopen.bmj.com/content/current [New issue; No digest content identified]

Bulletin of the World Health Organization

Volume 96, Number 12, December 2018, 797-864 http://www.who.int/bulletin/volumes/96/12/en/ [Reviewed earlier]

Child Care, Health and Development

Volume 44, Issue 6 Pages: 801-929 November 2018 https://onlinelibrary.wiley.com/toc/13652214/current [Reviewed earlier]

Clinical Therapeutics

November 2018 Volume 40, Issue 11, p1789-1956 http://www.clinicaltherapeutics.com/current [Reviewed earlier]

Clinical Trials

Volume 15 Issue 6, December 2018 http://journals.sagepub.com/toc/ctja/15/6 [Reviewed earlier]

Conflict and Health

http://www.conflictandhealth.com/ [Accessed 8 Dec 2018] [No new digest content identified]

Contemporary Clinical Trials

Volume 75 Pages 1-86 (December 2018) https://www.sciencedirect.com/journal/contemporary-clinical-trials/vol/75/suppl/C

[New issue; No digest content identified]

Current Opinion in Infectious Diseases

December 2018 - Volume 31 - Issue 6 https://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx [Reviewed earlier]

Developing World Bioethics

Volume 18, Issue 3 Pages: 205-306 September 2018 https://onlinelibrary.wiley.com/toc/14718847/current

SPECIAL ISSUE: AFRICAN PERSPECTIVES IN GLOBAL BIOETHICS

[Reviewed earlier]

Development in Practice

Volume 29, Issue 1, 2019 http://www.tandfonline.com/toc/cdip20/current [Reviewed earlier]

Disasters

Volume 42, Issue 4 Pages: S159-S327 October 2018 https://onlinelibrary.wiley.com/toc/14677717/current **Disasters in Conflict Areas**

[Reviewed earlier]

EMBO Reports

01 November 2018; volume 19, issue 11 http://embor.embopress.org/content/19/11?current-issue=y [New issue; No digest content identified]

Emerging Infectious Diseases

Volume 24, Number 12—December 2018 http://wwwnc.cdc.gov/eid/
[New issue; No digest content identified]

Epidemics

Volume 25 Pages 1-112 (December 2018) https://www.sciencedirect.com/journal/epidemics/vol/25/suppl/C [Reviewed earlier]

Epidemiology and Infection

Volume 146 - Issue 16 - December 2018 https://www.cambridge.org/core/journals/epidemiology-and-infection/latest-issue [Reviewed earlier]

The European Journal of Public Health

Volume 28, Issue 5, 1 October 2018 https://academic.oup.com/eurpub/issue/28/5 [Reviewed earlier]

Genome Medicine

https://genomemedicine.biomedcentral.com/articles [Accessed 24 Nov 2018] [No new digest content identified]

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)

Vol. 6, No. 3 October 03, 2018 http://www.ghspjournal.org/content/current [Reviewed earlier]

Global Public Health

Volume 14, 2019 Issue 1 http://www.tandfonline.com/toc/rgph20/current [Reviewed earlier]

Globalization and Health

http://www.globalizationandhealth.com/ [Accessed 8 Dec 2018] [No new digest content identified]

Health Affairs

Vol. 37 , No. 11 November 2018 https://www.healthaffairs.org/toc/hlthaff/current **Patient Safety**

[New issue; No digest content identified]

Health and Human Rights

Volume 20, Issue 2, December 2018

https://www.hhrjournal.org/volume-20-issue-2-december-2018/

Issue 20.2 features a special section: Special Section on Human Rights and the Social Determinants of Health and a General Papers section EDITORIAL

<u>Deepening the Relationship between Human Rights and the Social Determinants of</u> Health: A Focus on Indivisibility and Power

Kristi Heather Kenyon, Lisa Forman, and Claire E. Brolan

...The CSDH report prompted a special issue in Health and Human Rights in 2010 exploring the relationship between human rights and the social determinants of health.[2] Since then, there have been several critical global policy initiatives, including the Rio Declaration on the Social Determinants of Health (2011) and the Sustainable Development Goals (SDGs) (2015), which affirmed the links made by the CSDH locating the social determinants of health in relation to human rights and the right to health.[3] These complimentary frames are at last connected in rhetoric and policy, but what does this linkage mean in practice, and what progress has been made since 2009?[4]

<u>Social Medicine in Practice: Realizing the American Indian and Alaska Native Right</u> to Health

Lucas Trout, Corina Kramer, and Lois Fischer

<u>A Meta-Narrative Literature Synthesis and Framework to Guide Future Evaluation of</u> Legal Empowerment Interventions

Katherine Footer, Michael Windle, Laura Ferguson, Jordan Hatcher, Carrie Lyons, Emma Gorin, Anne L. Stangl, Steven Golub, Sofia Gruskin, and Stefan Baral

General Papers

<u>Human Subject Research: International and Regional Human Rights Standards</u> Andrés Constantin

Abstract

This article will place the discussion of human subject research within the larger context of human rights law, both at the international and regional level, and examine existing normative human rights frameworks that can be used to protect research subjects. The traditional approach has commonly focused on the ethical aspects of human subject research and little has been said about the implications of human experimentation on the enjoyment of basic rights. The difference between ethical principles and human rights is clearly determined by the non-enforceability of ethical norms and the legally binding nature of human rights obligations. A human rights approach to bioethics, and particularly to human subject research, can bring about a defined system and universally accepted set of rules in a field where sociocultural and religious diversity come into play.

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

Issue in Progress
https://www.liebertpub.com/toc/heq/2/1
[Reviewed earlier]

Health Policy and Planning

Volume 33, Issue 9, 1 November 2018 https://academic.oup.com/heapol/issue/33/9 [Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content [Accessed 8 Dec 2018] [No new digest content identified]

Humanitarian Exchange Magazine

Number 73, October 2018

https://odihpn.org/magazine/mental-health-and-psychosocial-support-in-humanitarian-crises/ **Rohingya refugees in Bangladesh: the humanitarian response**

More than 700,000 Rohingya refugees have arrived in Bangladesh since 25 August 2017 fleeing violence and persecution in Rakhine State, Myanmar. Over a million are sheltering in overcrowded camps without adequate assistance or protection. Stateless in Myanmar and denied refugee status in Bangladesh, the Rohingya have few rights or freedoms. Monsoons and cyclones are causing landslides, destroying shelters and infrastructure and disrupting services.

This edition of Humanitarian Exchange focuses on the humanitarian response to the Rohingya crisis. In the lead article, <u>Mark Bowden</u> outlines the historical, local and national political context in Bangladesh, and its operational implications. <u>Amal de Chickera</u> highlights the links between statelessness and displacement, and the international community's failure to prioritise human rights in its dealings both with Bangladesh and with Myanmar. <u>Puttanee Kangkun and John Quinley</u> document the persistent persecution and denial of rights the Rohingya have faced for decades. <u>Jeff Crisp</u> reflects on the premature, involuntary and unsafe return of Rohingya refugees to Myanmar in the 1970s and 1990s, and asks whether this could happen again.

<u>Sally Shevach and colleagues</u> explore how the 'localisation' agenda has influenced the operational response, and <u>Kerrie Holloway</u> draws on research by the Humanitarian Policy Group to test the common assumption that local actors necessarily have a better understanding of people's needs. <u>Nasif Rashad Khan</u> and colleagues and <u>Ashish Banik</u> reflect on their experiences of engaging with the international humanitarian response system. <u>Margie Buchanan-Smith and Marian Casey-Maslen</u> discuss evaluation findings relating to communication and community engagement, a theme taken up by <u>Nick Van Praag and Kai Hopkins</u>, who report on a Ground Truth survey on refugees' perceptions of assistance. <u>Julia Brothwell</u> discusses the British Red Cross/Bangladesh Red Crescent involvement in disaster preparedness and risk reduction during

the monsoon season, and <u>Gina Bark, Kate White and Amelie Janon</u> outline the consequences of long-term exclusion from basic healthcare services in increasing vulnerability to preventable diseases. <u>Matthew Wencel and colleagues</u> round off the issue with reflections on data collection coordination and other challenges associated with monitoring large concentrations of refugees.

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)

Volume 14, Issue 10, 2018

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

Issue Special Focus: Vaccination in Africa

[Reviewed earlier]

Infectious Agents and Cancer

http://www.infectagentscancer.com/content [Accessed 8 Dec 2018] [No new digest content identified]

Infectious Diseases of Poverty

http://www.idpjournal.com/content [Accessed 8 Dec 2018] [No new digest content identified]

International Health

Volume 10, Issue 6, November 2018 http://inthealth.oxfordjournals.org/content/current [Reviewed earlier]

International Journal of Community Medicine and Public Health

Vol 5, No 12 (2018) December 2018 http://www.ijcmph.com/index.php/ijcmph/issue/view/45 [Reviewed earlier]

International Journal of Epidemiology

Volume 47, Issue 6, 1 December 2018 https://academic.oup.com/ije/issue/47/5
Opinion

<u>Mobilizing an underused resource: cohort studies for population health intervention</u> research

Nancy Edwards; Ronald C Plotnikoff

International Journal of Epidemiology, Volume 47, Issue 6, 1 December 2018, Pages 1730–1733, https://doi.org/10.1093/ije/dyy191

Methods

Reducing contamination risk in cluster-randomized infectious disease-intervention trials

Robert S McCann; Henk van den Berg; Willem Takken; Amanda G Chetwynd; Emanuele Giorgi International Journal of Epidemiology, Volume 47, Issue 6, 1 December 2018, Pages 2015—2024, https://doi.org/10.1093/ije/dyy213

International Journal of Human Rights in Healthcare

Volume 11 Issue 5 2018 https://www.emeraldinsight.com/toc/ijhrh/11/5 [Reviewed earlier]

International Journal of Infectious Diseases

December 2018 Volume 77, p1-118 https://www.ijidonline.com/issue/S1201-9712(18)X0012-5 [Reviewed earlier]

IRB: Ethics & Human Research

November-December 2018 Volume: 40 Issue: 6

https://www.thehastingscenter.org/publications-resources/irb-ethics-human-research/ Feature Article

<u>Financial Payments for Participating in Research While Incarcerated: Attitudes of Prisoners</u>

By Divya Ravi, Paul P. Christopher, Eliza J. Filene, Sarah Ailleen Reifeis, and Becky L. White *Abstract:*

The practice of paying prisoners to for their participation in research has long been debated, and the controversy is reflected in the differing policies in the U.S. prison systems. Empirical study of financial payments to inmates who enroll in research has focused on whether this practice is coercive. In this study, we examined whether monetary incentives have the potential to be unduly influential among fifty HIV-positive prisoners. The majority of prisoners surveyed believed that inmates should receive some compensation for their involvement in research and disagreed with statements suggesting that the offer of payment constitutes undue influence. However, a sense of potentially being susceptible to undue influence was significantly higher among participants who had spent a longer time in prison and had less education. Overall, our findings suggest that most prisoners feel that they would be able to make a decision about research enrollment that is not solely based on an offer of monetary payment.

Article

Broad Consent for Future Research: International Perspectives

By Mark A. Rothstein, Heather L. Harrell, Katie M. Saulnier, Edward S. Dove, Chien Te Fan, Tzu-Hsun Hung, Obiajulu Nnamuchi, Alexandra Obadia, Gil Siegal, and Bartha Maria Knoppers Abstract:

In the United States, final amendments to the Federal Policy for the Protection of Human Subjects ("the Common Rule") were published on January 19, 2017, and they will take effect on January 21, 2019. One of the most widely discussed provisions is that for the first time, federal regulations governing research with humans authorize the use of broad consent for future,

unspecified research on individually identifiable biospecimens and associated data. Many questions have been raised about broad consent, including what effect it will have on research and whether it adequately protects the interests of research participants.

There are lessons to be learned for the U.S. and other countries by looking to countries that already have experience with broad consent for biobank collection and with the storage and subsequent use of the biospecimens and data. This article describes how broad consent works in five countries—Canada (in Quebec), Israel, Nigeria, Taiwan, and the United Kingdom—and with different types of biobanks: national biobanks, federated biobanks, and regional biobanks. Evaluating the provisions and challenges of the broad consent approaches in these countries can inform policies for this increasingly used approach to biobank regulation.

Article

The Ethics of Net-Risk Pediatric Research: Implications of Valueless and Harmful Studies

By David Wendler

Abstract:

Net-risk pediatric research encompasses interventions and studies that pose risks and do not offer a compensating potential for clinical benefit. These interventions and studies are central to efforts to improve pediatric clinical care. Yet critics argue that it is unethical to expose children to research risks for the benefit of unrelated others. While a number of ethical justifications have been proposed, none have received widespread acceptance. This leaves funders with uncertainty over whether they should support and institutional review boards with uncertainty over whether they should approve net-risk pediatric research. To try to answer these questions, this article describes a justification that I previously proposed and considers two objections to it. This analysis reveals that the opportunity to contribute to a valuable project can justify exposing children to risks even though some trials turn out to be valueless and others turn out to be harmful. It follows that, to protect pediatric participants, institutional review boards need to assess whether trials have the potential to collect socially valuable information and whether they are likely to enroll and retain a sufficient number of participants.

JAMA

December 4, 2018, Vol 320, No. 21, Pages 2171-2280

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

[New issue; No digest content identified]

Viewpoint

Evolving Issues in Oncology

Vaccines as an Integral Component of Cancer Immunotherapy

Jeffrey Schlom, PhD; James L. Gulley, MD, PhD

Abstract

It is important to distinguish vaccines designed to prevent cancer from those designed to treat cancer. The mode of action of the human papilloma virus (HPV) vaccine for the prevention of cervical and other HPV-associated malignancies is similar to that of vaccines for the prevention of infectious disease (ie, the induction of antibodies directed against essential components of the microbe). Even though there have been stunning successes in the area of preventive vaccines, the history of therapeutic cancer vaccines, which principally involve the development of cell-mediated immunity (ie, T cells) directed against tumor antigens, has been far more

challenging. However, the renaissance of cancer immunotherapy has rendered therapeutic cancer vaccines as a potential integral component of treatment.

Editorial

Oncology in Transition - Changes, Challenges, and Opportunities

Deborah Schrag, MD, MPH; Ethan Basch, MD, MSc

Abstract

Contemporary challenges and changes in the field of oncology reflect and often magnify medicine more broadly. Morbidity and mortality are often substantial, treatment is expensive, and management is complex necessitating interdisciplinary coordination across every field of medicine. The recent emergence of immunotherapy and adoptive cellular therapy has generated tremendous excitement because these approaches can sometimes achieve cure or durable responses, even in the setting of advanced cancer.

JAMA Pediatrics

December 2018, Vol 172, No. 12, Pages 1111-1208 http://archpedi.jamanetwork.com/issue.aspx Viewpoint

Need for Automated Interactive Genomic Interpretation and Ongoing Reanalysis

Mahdi Sarmady, PhD; Ahmad Abou Tayoun, PhD

JAMA Pediatr. 2018;172(12):1113-1114. doi:10.1001/jamapediatrics.2018.2675

This Viewpoint discusses advances in genetic testing and the need for automated interactive genomic interpretation and ongoing reanalysis to fully take advantage of those advances.

Editorial

Defining the Value of Treatments of Rare Pediatric Conditions

Lisa A. Prosser, PhD

JAMA Pediatr. 2018;172(12):1123-1124. doi:10.1001/jamapediatrics.2018.3343 Abstract

In this issue of JAMA Pediatrics, Whittington et al<u>1</u> present a comprehensive analysis of the projected long-term outcomes and cost-effectiveness of a chimeric antigen receptor T-cell therapy, tisagenlecleucel, for relapsed or refractory leukemia in children; this is the first gene therapy approved by the US Food and Drug Administration. The study uses a modeling approach and highlights 2 critical issues in defining value for an innovative treatment with limited evidence: the methodological challenges of applying economic evaluation techniques to rare pediatric conditions and reliably assessing value and affordability for very costly new treatments (in this case, \$475 000 per patient).

JBI Database of Systematic Review and Implementation Reports

November 2018 - Volume 16 - Issue 11 http://journals.lww.com/jbisrir/Pages/currenttoc.aspx [New issue; No digest content identified]

Journal of Adolescent Health

December 2018 Volume 63, Issue 6, p663-804

https://www.jahonline.org/issue/S1054-139X(17)X0027-X [Reviewed earlier]

Journal of Community Health

Volume 43, Issue 6, December 2018 https://link.springer.com/journal/10900/43/6/page/1 [Reviewed earlier]

Journal of Empirical Research on Human Research Ethics

Volume 13 Issue 5, December 2018 http://journals.sagepub.com/toc/jre/current [Reviewed earlier]

Journal of Epidemiology & Community Health

December 2018 - Volume 72 - 12 https://jech.bmj.com/content/72/12 [New issue; No digest content identified]

Journal of Evidence-Based Medicine

Volume 11, Issue 4 Pages: 217-291 November 2018 https://onlinelibrary.wiley.com/toc/17565391/current

The "architect analogy" of evidence-based practice: Reconsidering the role of clinical expertise and clinician experience in evidence-based health care

Arsenio Paez Pages: 219-226

First Published: 16 November 2018

Abstract

The role of expertise in evidence-based medicine (EBM) and practice (EBP) has long been debated. In the early years of the EBP movement, the role of expertise and experience were diminished in clinical decision-making. However, the concepts of EBP are evolving. A more nuanced view of the value of clinician expertise, based on experience and clinical judgement, has emerged. This article proposes that clinical expertise does not belong within the evidence hierarchy's decision-making pyramid as the lowest form of evidence, but rather alongside it, representing a complementary source of knowledge that supports the processes of EBP. An "Architect Analogy of EBP" is proposed as a new model by which to describe this relationship. In this analogy, the clinician's use of expertise is likened to the role of an architect, using evidence as building blocks in the construction of the client's edifice, representing the patients' health and wellbeing. Much as an architect carefully designs the edifice in consultation with the client's needs and preferences, choosing appropriate material (evidence), rejecting faulty material, and ensuring construction stays on course, the clinician must sort through a plethora of sometimes contradictory evidence, evaluate its merits and appropriateness for the patients' unique biopsychosocial circumstances and values, and monitor the effects of interventions on patients' health and wellbeing. The expertise of practitioners, as the architects of EBP, is an important

supporting source of knowledge that facilitates the "Five Steps of EBP," informs and facilitates EBP, and supports patient-centred care.

Journal of Global Ethics

Volume 14, Issue 1, 2018
http://www.tandfonline.com/toc/rjge20/current

**Special Issue: Education and Migration

[Reviewed earlier]

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

Volume 29, Number 4, November 2018 https://muse.jhu.edu/issue/39355 [Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 20, Issue 6, December 2018 https://link.springer.com/journal/10903/20/6/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, 8 Dec 2018 https://academic.oup.com/jid/issue/217/1 [Reviewed earlier]

Journal of Medical Ethics

December 2018 - Volume 44 - 12 http://jme.bmj.com/content/current [New issue; No digest content identified]

Journal of Medical Internet Research

Vol 20, No 11 (2018): November https://www.jmir.org/2018/11 [Reviewed earlier]

Journal of Medical Microbiology

Volume 67, Issue 11, November 2018 http://jmm.microbiologyresearch.org/content/journal/jmm/67/11 [Reviewed earlier]

Journal of Patient-Centered Research and Reviews

Volume 5, Issue 4 (2018) https://digitalrepository.aurorahealthcare.org/jpcrr/ [Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)

Volume 7, Issue 3, September 2018 https://academic.oup.com/jpids/issue [Reviewed earlier]

Journal of Pediatrics

December 2018 Volume 203, p1-470 http://www.jpeds.com/current [Reviewed earlier]

Journal of Pharmaceutical Policy and Practice

https://joppp.biomedcentral.com/ [Accessed 8 Dec 2018] Review

4 December 2018

Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region.

Authors: Ellen F. M. 't Hoen, Tapiwanashe Kujinga and Pascale Boulet Abstract

High medicines prices increasingly pose challenges for universal access to treatments of communicable and non-communicable diseases. New essential medicines are often patent-protected which sustains high prices in many countries, including in low- and middle-income countries. To respond to the HIV/AIDS crisis of the late nineties and to increase access to antiretroviral treatment, certain flexibilities contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS flexibilities) have been clarified and in some respects strengthened at the global level. They have been applied by a number of countries to ensure access to lower-priced generic medicines to treat HIV/AIDS. Governments in the South African Development Community (SADC) have also used TRIPS flexibilities to gain access to lower-priced generic medicines. This paper documents 15 instances of the use of TRIPS flexibilities by eight SADC Member States during the period 2001–2016. Of those, six concerned least developed countries (LDCs) that declared non-enforcement of pharmaceutical patents pursuant to a new LDC transition provision. All instances occurred in the context of medicines procurement for HIV treatment. Such flexibilities can, however, also be used to overcome patent barriers to gain access to generic medicines for other diseases, including NCDs. The

SADC, being a regional bloc with over 50% least developed country Members, can make use of the regional exception, a TRIPS flexibility that facilitates the production or procurement of generic medicines to the benefit of the entire region. SADC's Pharmaceutical Business Plan proposes strategies for increased collaboration and pooled procurement of medicines.

Journal of Public Health Management & Practice

November/December 2018 - Volume 24 - Issue 6 https://journals.lww.com/jphmp/pages/currenttoc.aspx [Reviewed earlier]

Journal of Public Health Policy

Volume 39, Issue 4, November 2018 https://link.springer.com/journal/41271/39/4/page/1 [Reviewed earlier]

Journal of the Royal Society – Interface

November 2018; volume 15, issue 148 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

December 2018; Volume 92,Issue 24 http://jvi.asm.org/content/current [New issue; No digest content identified]

The Lancet

Dec 08, 2018 Volume 392 Number 10163 p2413-2514 https://www.thelancet.com/journals/lancet/issue/current Editorial

CRISPR-Cas9: a world first?

The Lancet

On Nov 26, when the world heard the claims that the first genetically edited children had been born, the reaction was one of deep and profound shock. He Jiankui announced on the eve of the Second International Summit on Human Genome Editing in Hong Kong that the CRISPR-Cas9 gene editing technique had been used to edit the genome of twin girls born earlier that

month in China. It seemed that the world had changed weeks ago and we were just catching up.

Although human germline editing has been done, the embryos have never been allowed to develop to full term. The CRISPR-Cas9 technique is in its infancy and data is still emerging on the potential for off-target gene editing and mosaicism, meaning that not all copies of the target gene are edited. Targeting the CCR5 gene has also been widely criticised. The girls, whose genomes were apparently healthy before editing, were born to an HIV-negative mother and an HIV-positive father, however, CCR5 is just one of the potential route for HIV entry into the cell, which is not the most common HIV cell-entry pathway within Chinese populations. This was also not a situation of unmet medical need, since there are well-established and effective ways to prevent transmission of HIV or to treat it. Moreover, the role of CCR5 in the immune system is not fully understood, the girls may be more susceptible to other infections. It has become clear that this is really is no more than a human experiment, a proof of concept unlikely to confer any real benefit to the recipients but with unknown and potentially incredibly serious risks.

The international response to this experiment has been swift, with widespread condemnation and criticism. The Chinese Academy of Medical Sciences, Chinese Academy of Engineering, and Chinese Academy of Sciences called attention to the prohibition of genetic manipulation of human gametes, zygotes, and embryos for reproductive purposes in China, and called for stronger ethics committees and better ethical education. Marcia McNutt and Victor Dzau, presidents of the US National Academies of Sciences and Medicine respectively, issued a joint statement raising deep concerns that the researcher did not follow the National Academies 2017 recommendations or other international norms of scientific conduct, and stressed the need for more specific standards and principles agreed by the international community.

Since the announcement, the scientific community has begun to reflect more deeply. Many experts had suggested that this development was imminent. Were we guilty of looking away and allowing this to happen? Not according to Dominic Wilkinson, neonatologist and professor of medical ethics from the University of Oxford, who told The Lancet "this was not a case of science outpacing ethical guidance or the law. There were guidelines in place that warned against research of this sort. This appears to be a researcher who had no interest in attending to ethical guidelines relating to scientific research." Wilkinson asserts that these researchers have undermined the contract that scientists have with society; that contract allows research in situations where the risk to the patient is clearly calculated and the implications to the community at large have been appropriately considered. By ignoring these risks, this research team has potentially undermined community trust in research and technology and this threatens the research endeavour more generally along with research into this potentially important technology.

Scientific culture has long been to accredit individuals with steps forward instead of recognising group achievement or incremental progress. This has created an ethos of celebrity in academia, which has sometimes rewarded maverick behaviour. The increasing speed of scientific research—from conference late breakers to techniques for rapid and public dissemination of research that come with less critical oversight—adds to a constant fear of getting scooped. These factors, combined with strong incentives for research and a less regulated research

framework, have created an atmosphere in which some scientists seem ready to act outside of clear ethical frameworks.

Although it seemed like the world had changed overnight with the birth of these twin girls, it will be the reaction of the scientific and wider communities that has the power to determine the path of these irrevocable changes. How this case is handled will set a precedent for the future, determining in part whether this development ultimately accelerates progress towards a useful and safe therapeutic intervention or whether the consequences of the broken compact between science and society will be to delay this and other innovative technologies.

Comment

A global accountability mechanism for access to essential medicines

Mariângela Simão, Veronika J Wirtz, Lubna A Al-Ansary, Suzanne Hill, John Grove, Andrew L Gray, Claudia Nannei, Lisa Hedman, Pamela Das, Hans Hogerzeil
Access to affordable, quality-assured essential medicines is a prerequisite for effective universal health coverage. 1,2 Efforts to ensure comprehensive access to essential medicines have been hindered by a dearth of information. Most monitoring efforts have focused on measurement of a prespecified list of essential medicines in health facilities. Measures of affordability in private and public health facilities have relied on periodic surveys, usually by non-governmental organisations (NGOs) or academia The quality of medicine products and of prescribing practice, as well as patients' use of essential medicines, have been assessed even less often. Pharmaceutical expenditure in the public and private sector is not prioritised in national systems, and is rarely reported. Without systematic data reporting on national pharmaceutical expenditure, there is a lack of attention to access to essential medicines in major reports such as the World Health Statistics. The 2015 Millennium Development Goals Task Force report concluded that tracking progress on access to essential medicines was impossible, given the absence of country-level data. 6, 7

When target measurements are used to improve access, a robust monitoring and accountability system is needed—eg, the three-step framework recommended by Paul Hunt, former UN Special Rapporteur on the Right to Health, that involves appropriate collection of data, independent review, and the necessary corrective action. The Lancet Commission on Essential Medicines Policies made an initial proposal for such a framework. Independent review and corrective action are important components of an accountability mechanism, as shown by UNAIDS' HIV progress reports and work in reproductive, maternal, newborn, child, and adolescent health. 10

Members of the Lancet Commission on Essential Medicines Polices and WHO have discussed options for such a framework. A global accountability mechanism for monitoring access to essential medicines must take account of major global trends—eg, strengthening patient-centred primary health care; efficient country-led horizontal health systems, including prevention and treatment of non-communicable diseases; systems of risk-sharing, pre-payment, and social health insurance; and greater attention to the quality of care, the quality of health products, the skills and attitudes of health workers, and cost-effective treatment. Civil society is also demanding better data collection, transparency, and systems of accountability to promote equity and good governance. 11 Greater reliance on routine data facilitated by new technologies, including mobile applications, should enable countries to generate timely information on a continuous basis.

The focus of accountability should move away from measuring only availability of medicines towards the effectiveness, quality, and efficiency of patient-centred comprehensive primary care services, which encompasses equitable access to essential medicines. To advance this agenda, indicators are therefore needed that are sensitive to differences in access on the basis of gender, ethnicity, education, residential location, and wealth quintile. WHO has already provided resources to assist national programmes in applying an equity lens. 12, 13 Under the aegis of WHO, medicine access indicators should now be developed in close collaboration with member states, academia, and civil society, consisting of a small set of screening indicators supported by more detailed diagnostic and progress indicators.

Further high-level discussions between WHO, the Lancet Commission, other UN agencies, and NGOs have led to the identification of four priorities to ensure the development of a global Accountability Mechanism for Access to Essential Medicines (abbreviated as 2A2M). First, high-level political support is needed through the definition of the accountability structure and operating mechanisms, taking into consideration the roles and responsibilities of national governments, academic partners, and civil society. Second, the strategic generation, analysis, and use of prioritised data for decision making is vital, with a strong focus on national capacity building and leveraging existing technical support programmes. Third, technological advances in data collection must be adopted, building on the principles of the Health Data Collaborative and existing data platforms and recognising variability in national digital maturity. Finally, global advocacy is needed to ensure the engagement of all relevant technical and financial contributors at national and international levels.

A global accountability mechanism for access to essential medicines that is nationally applicable and feasible will take several years to achieve. However, experiences in HIV and reproductive, maternal, newborn, child, and adolescent health have shown that it can be done, provided a clear political mandate and the necessary financial and technical resources are ensured, together with country leadership and the engagement of civil society and academic institutions.

VJW reports grants from Sandoz International GmbH and from the International Federation of the Pharmaceutical Manufacturer Associations outside the submitted work. HH reports personal fees from WHO, Health Action International, and Access to Medicines Index 2018, outside the submitted work. PD is Senior Executive Editor, The Lancet. We declare no other competing interests. The authors alone are responsible for the views expressed in this Comment and they do not necessarily represent the views, decisions, or policies of the institutions with which they are affiliated.

Review

The 2018 report of the Lancet Countdown on health and climate change: shaping the health of nations for centuries to come

Nick Watts, Markus Amann, Nigel Arnell, Sonja Ayeb-Karlsson, Kristine Belesova, Helen Berry, Timothy Bouley, Maxwell Boykoff, Peter Byass, Wenjia Cai, Diarmid Campbell-Lendrum, Jonathan Chambers, Meaghan Daly, Niheer Dasandi, Michael Davies, Anneliese Depoux, Paula Dominguez-Salas, Paul Drummond, Kristie L Ebi, Paul Ekins, Lucia Fernandez Montoya, Helen Fischer, Lucien Georgeson, Delia Grace, Hilary Graham, Ian Hamilton, Stella Hartinger, Jeremy Hess, Ilan Kelman, Gregor Kiesewetter, Tord Kjellstrom, Dominic Kniveton, Bruno Lemke, Lu Liang, Melissa Lott, Rachel Lowe, Maquins Odhiambo Sewe, Jaime Martinez-Urtaza, Mark

Maslin, Lucy McAllister, Slava Jankin Mikhaylov, James Milner, Maziar Moradi-Lakeh, Karyn Morrissey, Kris Murray, Maria Nilsson, Tara Neville, Tadj Oreszczyn, Fereidoon Owfi, Olivia Pearman, David Pencheon, Steve Pye, Mahnaz Rabbaniha, Elizabeth Robinson, Joacim Rocklöv, Olivia Saxer, Stefanie Schütte, Jan C Semenza, Joy Shumake-Guillemot, Rebecca Steinbach, Meisam Tabatabaei, Julia Tomei, Joaquin Trinanes, Nicola Wheeler, Paul Wilkinson, Peng Gong, Hugh Montgomery, Anthony Costello

The Lancet Countdown: tracking progress on health and climate change was established to provide an independent, global monitoring system dedicated to tracking the health dimensions of the impacts of, and the response to, climate change. The *Lancet* Countdown tracks 41 indicators across five domains: climate change impacts, exposures, and vulnerability; adaptation, planning, and resilience for health; mitigation actions and health co-benefits; finance and economics; and public and political engagement.

This report is the product of a collaboration of 27 leading academic institutions, the UN, and intergovernmental agencies from every continent. The report draws on world-class expertise from climate scientists, ecologists, mathematicians, geographers, engineers, energy, food, livestock, and transport experts, economists, social and political scientists, public health professionals, and doctors...

Lancet Global Health

Dec 2018 Volume 6 Number 12 e1253-e1404 http://www.thelancet.com/journals/langlo/issue/current [Reviewed earlier]

Lancet Infectious Diseases

Dec 2018 Volume 18 Number 12 p1289-1410 e368-e407 http://www.thelancet.com/journals/laninf/issue/current [Reviewed earlier]

Lancet Respiratory Medicine

Dec 2018 Volume 6 Number 12 p885-962 e56-e57 http://www.thelancet.com/journals/lanres/issue/current [Reviewed earlier]

Maternal and Child Health Journal

Volume 22, Issue 12, December 2018 https://link.springer.com/journal/10995/22/12/page/1 [Reviewed earlier]

Medical Decision Making (MDM)

Volume 38 Issue 8, November 2018 http://mdm.sagepub.com/content/current [Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy Volume 96, Issue 3 Pages: 409-605 September 2018 https://onlinelibrary.wiley.com/toc/14680009/current [Reviewed earlier]

Nature

Volume 564 Issue 7734, 6 December 2018 http://www.nature.com/nature/current_issue.html Editorial | 05 December 2018

How to respond to CRISPR babies

The claims from He Jiankui that he has used gene editing to produce twin girls demand action. A new registry of research is a good start.

Nature Medicine

Volume 24 Issue 12, December 2018 https://www.nature.com/nm/volumes/24/issues/12 Editorial | 06 December 2018

Diversifying clinical trials

Scientific common sense and social justice dictate that the safety and efficacy of new therapies must be tested in the patient populations in need of treatment. Yet a recent study found that African Americans have been dramatically underrepresented in US clinical trials for cancer drugs. Efforts to increase the participation of minorities in clinical trials must become a priority for all drug developers.

Among patient populations, the safety and efficacy of new treatments may vary with differences in sex, race, age or lifestyle, for example. Such variation in drug effects can only be detected by carrying out clinical trials on diverse patient populations, an aim that has a long history. In 1993, the US government passed a law that required the National Institutes of Health to ensure that federally funded clinical research prioritize the inclusion of women and minorities. More recently, in 2014, the US Food and Drug Administration (FDA) instituted an action plan that supports industry efforts at improving diversity in clinical trials. The following year, the FDA began publishing a 'Drug Trials Snapshot' that includes an analysis of the sex, race and age of clinical trial participants for every new drug approved.

Against this backdrop, the findings of a recent report (https://www.propublica.org/article/black-patients-miss-out-on-promising-cancer-drugs) by the nonprofit news organization ProPublica, co-published with the news outlet STAT, are disheartening. This report analyzed Snapshot data from clinical trials for the 31 cancer drugs approved by the FDA since 2015, comparing the demographics of these trials with the incidence of various cancers by race.

In trials for 24 of these 31 drugs, fewer than 5% of the patients were African American, despite the fact that African Americans make up 13.4% of the US population. For 18 of those drugs, the type of cancer targeted occurs in African Americans at least as frequently as in Americans of European descent. In trials for those types of cancer, on average only 4.1% of patients were

African American. And in trials for four multiple myeloma drugs, only 5% of the participants, on average, were African American, whereas 14% of people diagnosed with multiple myeloma are African Americans. A separate study by the FDA that analyzed clinical trials over a longer time frame similarly found that African-American patients make up only 4.5% of participants in multiple myeloma trials (Blood 130, 4352, 2017).

Many reasons have been put forward to explain the difficulties in enrolling African Americans in clinical trials. Chief among them is distrust of the medical establishment and fears of exploitation in medical research in this population (Am. J. Public Health 104, e16–e31, 2014). The infamous Tuskegee Study, in which the US Public Health Service deprived hundreds of African-American men of syphilis treatment so that researchers could study how the disease progressed, has cast a long shadow. In some communities, African Americans may also lack sufficient information regarding what clinical trials can offer and the safeguards in place to protect the privacy of their information. Beyond distrust and lack of information, substantial logistical hurdles can also impede fuller clinical trial participation. For example, some individuals may have limited access to the cancer centers that are the hubs of clinical studies, or they may lack the ability to take time off work to take part in a trial.

Recent findings may contribute to the wariness with which African Americans view medical research (Health Aff. (Millwood) 37, 1605–1614, 2018; https://www.statnews.com/2018/10/01/african-americans-clinical-trials). This report highlighted the high percentage (29%), relative to their proportion of the United States population as a whole, of African Americans included over the last two decades in clinical trials in which patients were not required to give consent. These trials involved, for example, testing emergency medical procedures under conditions where the patient is physically incapable of giving consent. Such studies are often conducted in large medical centers in areas where African Americans may suffer disproportionately from the particular conditions being studied. Nevertheless, for a community in which the issue of consent resonates deeply, the high inclusion rate of African Americans in trials where patient consent was not obtained may undermine attempts to increase their participation in clinical trials.

These efforts must involve ongoing investment by those conducting clinical trials in engaging with and building trust in African-American communities. From a logistical perspective, placing study sites in areas of community outreach may ease the burdens that members of those communities face in order to participate in clinical trials.

New technologies that foster the decentralization of clinical trials may also offer opportunities for increased access for African Americans as well as other minorities not currently well represented in clinical trials. Several recently developed websites offer matchmaking between patients and clinical trials, enabling patients to find appropriate clinical trials no matter where the patients are physically located.

Recent efforts to generate comprehensive health, genomic and lifestyle profiles of the population, such as the All of Us initiative, have heightened awareness of issues of population diversity. Although race is a social construct that does not have a strict relationship to genetics, ensuring a representative sampling of the population across racial and ethnic boundaries is clearly a priority of such studies that requires high levels of engagement with historically neglected communities. With increasing awareness of the roles that genetics and lifestyle play

in determining health and drug response, the time is now ripe to prioritize diversity in clinical trials.

Nature Reviews Immunology

Volume 18 Issue 12, December 2018 https://www.nature.com/nri/volumes/18/issues/12 [Reviewed earlier]

New England Journal of Medicine

November 29, 2018 Vol. 379 No. 22 http://www.nejm.org/toc/nejm/medical-journal [New issue; No digest content identified]

Pediatrics

December 2018, VOLUME 142 / ISSUE 6 http://pediatrics.aappublications.org/content/142/6?current-issue=y [New issue; No digest content identified]

Pharmaceutics

Volume 10, Issue 3 (September 2018) https://www.mdpi.com/1999-4923/10/3 [Reviewed earlier]

PharmacoEconomics

Volume 36, Issue 12, December 2018 https://link.springer.com/journal/40273/36/12/page/1 [Reviewed earlier]

PharmacoEconomics & Outcomes News

Volume 817, Issue 1, December 2018 https://link.springer.com/journal/40274/817/1/page/1 Meeting report

Assessing cost effectiveness of pneumococcal conjugate vaccines

Meeting report

Gender-neutral 9-valent HPV vaccine program cost effective

Clinical study

HBV and HCV screening cost effective in migrants

PLOS Currents: Disasters

http://currents.plos.org/disasters/ [Accessed 8 Dec 2018] [No new digest content identified]

PLoS Currents: Outbreaks

http://currents.plos.org/outbreaks/
[Accessed 8 Dec 2018]
[No new digest content identified]

PLoS Medicine

http://www.plosmedicine.org/ (Accessed 8 Dec 2018) [No new digest content identified]

PLoS Neglected Tropical Diseases

http://www.plosntds.org/ (Accessed 8 Dec 2018) [No new digest content identified]

PLoS One

http://www.plosone.org/ [Accessed 8 Dec 2018] Research Article

Beyond confidence: Development of a measure assessing the 5C psychological antecedents of vaccination

Cornelia Betsch, Philipp Schmid, Dorothee Heinemeier, Lars Korn, Cindy Holtmann, Robert Böhm

Research Article | published 07 Dec 2018 PLOS ONE https://doi.org/10.1371/journal.pone.0208601

Research Article

The relationship between perceptions and self-paid hepatitis B vaccination: A structural equation modeling approach

Yogambigai Rajamoorthy, Alias Radam, Niazlin Mohd Taib, Khalid Ab Rahim, Abram Luther Wagner, Mudatsir Mudatsir, Subramaniam Munusamy, Harapan Harapan | published 06 Dec 2018 PLOS ONE https://doi.org/10.1371/journal.pone.0208402

Research Article

Estimating everyday risk: Subjective judgments are related to objective risk, mapping of numerical magnitudes and previous experience

Hannah A. D. Keage, Tobias Loetscher published 05 Dec 2018 PLOS ONE https://doi.org/10.1371/journal.pone.0207356

PLoS Pathogens

http://journals.plos.org/plospathogens/ [Accessed 8 Dec 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 8 Dec 2018] [No new digest content identified]

Prehospital & Disaster Medicine

Volume 33 - Issue 5 - October 2018 https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue [Reviewed earlier]

Preventive Medicine

Volume 117, Pages 1-114 (December 2018)

https://www.sciencedirect.com/journal/preventive-medicine/vol/117/suppl/C

Behavior Change, Health, and Health Disparities 2018: Tobacco Regulatory Science Edited by Stephen T. Higgins

This Special Issue of Preventive Medicine (PM) is the 5th in a series on behavior change, health, and health disparities. Unhealthy behavior patterns (i.e., lifestyle choices) including cigarette smoking and other substance abuse, physical inactivity, unhealthy food choices, and non-adherence with recommended medical regimens, undermine U.S. population health by increasing risk for chronic disease and premature death. This Special Issue brings together scholarly contributions from the emerging area of tobacco regulatory science to examine current topics of critical importance to reducing the burden of cigarette smoking on U.S. population health. More specifically, three related topics are examined including (a) the potential for reducing smoking by adopting a national policy that would cap the nicotine content of cigarettes at minimally-addictive levels; (b) increasing scientific understanding of cigarette smoking and other tobacco use among populations that are especially vulnerable to initiating smoking, tobacco addiction, and its adverse health consequences; and (c) the potential of a harm-reduction strategy for reducing the burden of smoking by advocating that those who are unwilling or unable to quit nicotine use substitute electronic cigarettes or other non-combusted sources of nicotine for cigarettes in order to avoid exposure to the other toxins in tobacco smoke that are most responsible for smoking morbidity and mortality. While tremendous progress has been made in reducing overall U.S. smoking prevalence and its adverse health impacts, more needs to be done. This Special Issue offers some ideas that have the potential to make a substantive contribution towards that goal.

Proceedings of the Royal Society B

29 August 2018; volume 285, issue 1885 http://rspb.royalsocietypublishing.org/content/285/1885?current-issue=y [Reviewed earlier]

Public Health

December 2018 Volume 165, p1-156 http://www.publichealthjrnl.com/current [New issue; No digest content identified]

Public Health Ethics

Volume 11, Issue 3, November 2018
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Public Health Reports

Volume 133 Issue 1_suppl, November/December 2018 https://journals.sagepub.com/toc/phrg/133/1_suppl

From Local Action to National Progress on 5 Major Health Challenges: The Bloomberg American Health Initiative

Guest Editor: Joshua M. Sharfstein, Jessica Leighton, Alfred Sommer and Ellen J. MacKenzie
The articles in this supplemental issue of Public Health Reports provide insight into what it will
take for the field of public health to tackle 5 of the most complex and difficult health problems
of our time: (1) large numbers of adolescents disconnected from work and school; (2) violence
(including gun violence), intimate partner and sexual violence, and suicide; (3) opioid addiction
and overdose; (4) a dysfunctional food system associated with obesity; and (5) threats to the
environment.

These 5 problems are the central focus of the new Bloomberg American Health Initiative, which MacKenzie et all describe in their Commentary. "All 5 areas of focus are serious problems facing the nation, with deep connections to economic and social factors," they write. "None have quick fixes." Yet there is reason to believe that public health can lead the way toward meaningful progress.

From December 2017 to April 2018, the initiative held 5 national symposia to document the state of understanding and to inform a public health perspective on each challenge. This supplement includes these perspectives, as well as commentaries in the cross-cutting areas of evidence, policy, and equity. Together, these articles provide a road map for efforts to bring public health training to frontline organizations, pursue insights through innovative research, and advance effective programs, policies, and strategies for change...

Qualitative Health Research

Volume 28 Issue 14, December 2018 http://qhr.sagepub.com/content/current [Reviewed earlier]

Research Ethics

Volume 14 Issue 4, October 2018 http://journals.sagepub.com/toc/reab/current [Reviewed earlier]

Reproductive Health

http://www.reproductive-health-journal.com/content [Accessed 8 Dec 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
Recently Published Articles
[No new digest content identified]

Risk Analysis

Volume 38, Issue 12 Pages: 2503-2739 December 2018 https://onlinelibrary.wiley.com/toc/15396924/current **Communicating About Zika**

Editorial

Introduction to Special Series: Communicating About Zika

Dominique Brossard, Kathleen Hall Jamieson William Hallman

Pages: 2504-2506

First Published: 07 December 2018

Perspective Free Access

<u>Chronicling the Risk and Risk Communication by Governmental Officials During the Zika Threat</u>

Marin Pearson Allen Pages: 2507-2513

First Published: 12 November 2018

Abstract

The unique circumstances surrounding Zika, including the fact that it is both mosquito-borne and sexually transmissible, brought to the fore concerns about optimal ways to communicate risk in an environment characterized by rapidly evolving knowledge. The difficulty in doing so is magnified by the fact that science-based health messages from governmental agencies must be developed in an evidence-based, audience-participative, and collaborative manner. A recent reminder in JAMA asserted the importance of preparing now for future threats. Understanding how the knowledge and messaging about Zika changed across time should help public health officials prepare for such challenges.

Original Research Articles

Communicating Zika Risk: Using Metaphor to Increase Perceived Risk Susceptibility

Hang Lu, Jonathon P. Schuldt

Pages: 2525-2534

First Published: 27 February 2018

Risk Management and Healthcare Policy

Volume 11, 2018

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

[No new digest content identified]

Science

07 December 2018 Vol 362, Issue 6419 http://www.sciencemag.org/current.dtl *In Depth*

What now for human genome editing?

By Jon Cohen

Science07 Dec 2018: 1090-1092 Restricted Access

Claimed creation of CRISPR-edited babies triggers calls for international oversight.

For China, a CRISPR first goes too far

By Dennis Normile

Science07 Dec 2018: 1091 Restricted Access

Scientists and ethicists call for strengthened oversight in wake of He Jankui's announcement.

Science Translational Medicine

05 December 2018 Vol 10, Issue 470 http://stm.sciencemag.org/

[New issue; No digest content iden5ified]

Social Science & Medicine

Volume 219 Pages 1-86 (December 2018) https://www.sciencedirect.com/journal/social-science-and-medicine/vol/219/suppl/C [Reviewed earlier]

Systematic Reviews

https://systematicreviewsjournal.biomedcentral.com/articles [Accessed 8 Dec 2018] [No new digest content identified]

Travel Medicine and Infectious Diseases

Volume 26 Pages 1-78 (November–December 2018) http://www.travelmedicinejournal.com/

Tropical Medicine & International Health

Volume 23, Issue 12 Pages: i-iv, 1281-1407 December 2018

https://onlinelibrary.wiley.com/toc/13653156/current

Original Research Papers

<u>Comparison between the traditional (1997) and revised (2009) WHO classifications of dengue disease: a retrospective study of 30 670 patients</u>

Natal Santos da Silva, Eduardo A. Undurraga, Alice Tobal Verro, Maurício Lacerda Nogueira

Pages: 1282-1293

First Published: 03 October 2018

Abstract Objective

To compare WHO's traditional (1997) and revised (2009) guidelines for dengue classification, using a large sample of patients of all ages with varying clinical conditions from a dengue-endemic area in Brazil.

Methods

We compared 30 670 laboratory-confirmed dengue cases (1998–2012) using both WHO's dengue classification guidelines. Stereotype ordinal logistic regressions were used to analyse the association between patients' demographics and signs and symptoms related to dengue infection severity, as defined in the 1997 and 2009 guidelines. We then compared the degree of agreement in dengue classification of both guidelines.

Results

Dengue signs and symptoms in patients were poorly correlated to disease severity as defined by both guidelines (Cramer's V test <0.2). Hypotensive shock was the exception for both classifications, presenting dependence (Z = 56.42; P < 0.001, and Z = 55.24; P < 0.001) and high agreement (Cramers's V = 1; P < 0.001, and Cramers's V = 0.97; P < 0.001) for WHO 1997 and 2009, respectively. Last, we also found substantial agreement in disease classification between both guidelines (Kendall tau-b = 0.79; P < 0.001), although 2009 guidelines were more sensitive in the detection of severe cases.

Conclusions

We hope our results will inform the debate about dengue classification guidelines, particularly concerning clinical value, study comparability, and ways in which future guidelines can support the clinical management of dengue. Our results suggest that caution should be taken when using WHO guidelines to assess dengue severity to improve clinical management of patients. Open Access

The health consequences of falsified medicines- A study of the published literature

<u>Mohammad Sofiqur Rahman, Naoko Yoshida, Hirohito Tsuboi, Naoki Tomizu, Jamie Endo, Onishi Miyu, Yoshio Akimoto, Kazuko Kimura</u>

Pages: 1294-1303

First Published: 06 October 2018

Abstract Objectives

To analyse and present the literature describing the health consequences of falsified medicines, focusing on mortality and morbidity, as well as the scale of the issue, the geographic extent, the medicines affected, and the harm caused at both the individual and population levels.

Methods

We searched for articles in PubMed, using pre-optimized keywords '(counterfeit OR fake OR bogus OR falsified OR spurious) AND (medicine OR drug)'. Searches up to February 2017 yielded 2006 hits, of which 1791 were full-length articles in English. Among them, we found 81 papers that qualitatively or quantitatively described 48 incidents in which falsified medicines caused patients to suffer serious adverse effects, injury, symptoms or death. Results

The distribution of incidents was examined according to the economic status of the countries involved, regional location in the world, therapeutic category of the medicines, number of incidents and victims by year, and characteristics of the falsified medicines. Among the 48 reported incidents, 27 (56.3%) occurred in developing countries and 21 (43.7%) in developed countries. These incidents involved a total of approximately 7200 casualties including 3604 deaths.

Conclusions

Despite the poor quality of much of the reported data, the results of this study indicate that all types of medications have been targeted for falsification, and falsified medicines have had a serious impact on the health of both adults and children worldwide, with similar numbers of incidents in developing and developed countries.

Vaccine

Volume 37, Issue 1 Pages 1-210 (3 January 2019) https://www.sciencedirect.com/journal/vaccine/vol/37/issue/1 Research article Full text access

Review of the economic evidence presented to the United States Advisory Committee on Immunization Practices, 2012–2016

Jamison Pike, Andrew J. Leidner, Jessica R. MacNeil, Amanda C. Cohn Pages 7-10

Research article Open access

<u>Prioritization of risk groups for influenza vaccination in resource limited settings – A case study from South Africa</u>

Meredith L. McMorrow, Stefano Tempia, Sibongile Walaza, Florette K. Treurnicht, ... Cheryl Cohen

Pages 25-33

Research article Full text access

<u>Impact of implementing a technology platform in community pharmacies to increase adult immunizations rates</u>

Nizar K. Wehbi, Rajvi J. Wani, Donald G. Klepser, Janice Murry, Ali S. Khan Pages 56-60

Research article Open access

<u>Mandatory policies for influenza vaccination: Views of managers and healthcare</u> workers in England

Martine Stead, Nathan Critchlow, Douglas Eadie, Fay Sullivan, ... Fiona Dobbie Pages 69-75

Research article Full text access

The effects of vaccination forecasts and value-based payment on adult immunizations by community pharmacists

Jennifer L. Bacci, Ryan Hansen, Christina Ree, Marci J. Reynolds, ... Peggy S. Odegard Pages 152-159

Research article Full text access

An environmental scan to examine stakeholder perspectives on human papillomavirus vaccination: A mixed methods study

Paige Lake, Monica L. Kasting, Teri Malo, Anna R. Giuliano, Susan T. Vadaparampil Pages 187-194

Vaccine: Development and Therapy

https://www.dovepress.com/vaccine-development-and-therapy-archive111 (Accessed 8 Dec 2018)
[No new digest content identified]

Vaccines — Open Access Journal

http://www.mdpi.com/journal/vaccines (Accessed 8 Dec 2018) Open Access Perspective

Clinical Trials and Administration of Zika Virus Vaccine in Pregnant Women: Lessons (that Should Have Been) Learned from Excluding Immunization with the Ebola Vaccine during Pregnancy and Lactation

by David A. Schwartz

Vaccines 2018, 6(4), 81; https://doi.org/10.3390/vaccines6040081 - 4 December 2018

Abstract

As evidenced from recent epidemics, both Ebola and Zika virus infection are potentially catastrophic when occurring in pregnant women. Ebola virus causes extremely high rates of mortality in both mothers and infants; Zika virus is a TORCH infection that produces a congenital malformation syndrome and pediatric neurodevelopmental abnormalities. Production of efficacious vaccines has been a public health priority for both infections. Unfortunately, during the clinical trials and subsequent deployment of a vaccine for the Ebola virus, pregnant and lactating women were, and continue to be, excluded from receiving the life-saving vaccine. The most serious consequence of Zika virus infection, congenital Zika syndrome, results from fetal infection during pregnancy. Thus, pregnant women have a major stake in the ongoing development of a vaccine for Zika virus. The exclusion of pregnant women from the development, clinical trials and administration of a potential Zika vaccine unfairly deprives them and their infants of the protection they need against this potentially catastrophic intrauterine infection. When creating policy about these issues, it is important to critically evaluate vaccine safety in pregnancy in the context of the substantial risk of infection for the pregnant woman and her fetus in the absence of immunization.

Value in Health

December 2018 Volume 21, Issue 12, p1355-1444

http://www.valueinhealthjournal.com/current [Reviewed earlier]

Viruses

2018, 10(11), 648 https://www.mdpi.com/1999-4915/10/11 [Reviewed earlier]

* * * *

<u>From Google Scholar & other sources: Selected Journal Articles, Newsletters, Dissertations, Theses, Commentary</u>

Medicina

Published: 3 December 2018

Awareness, Attitudes, and Practices Toward Meningococcal B Vaccine among Pediatricians in Italy

P Ferrara, L Stromillo, L Albano

Abstract: Background and objectives: Vaccination against bacterial pathogens is decisive for preventing invasive meningococcal disease and pediatricians play a pivotal role in vaccination compliance and coverage. The aim of this study was to investigate awareness, attitude, and practices toward the vaccine against Meningococcal B serogroup (4CMenB) among a sample of Italian pediatricians.

Materials and Methods: A cross-sectional study was carried out using an online questionnaire from March to May 2015. Three multivariate logistic regression models were built to identify factors associated with the outcomes of interest. Results: The data showed that 95.5% of the interviewees correctly responded about the availability of 4CMenB vaccine in Italy, while only 28.0% knew the vaccination schedule for children aged two years or under. This knowledge was significantly higher in younger pediatricians and in those who worked a higher number of hours per week. Pediatricians self-reported a positive attitude toward the utility and safety of 4CMenB vaccine. Those pediatricians with a strong positive attitude toward the utility of the vaccine, who knew the vaccination schedules for children of two years or under, and who declared a satisfactory or good knowledge about the vaccine were more likely to inform parents about its availability in Italy, recommend the vaccination, and verify patients' vaccination status, in their daily practice. Conclusions: The study highlights factors that currently influence pediatricians' practices regarding the 4CMenB vaccine. The results showed the possible actions recommended to improve physicians' awareness and behaviors in order to improve the vaccination compliance and invasive meningococcal diseases prevention.

Journal of Constitutional Law -University of Pennsylvania

October 2018

Litigating Alternative Facts: School Vaccine Mandates in the Courts

DR Reiss ABSTRACT In June 2015, California's governor signed into law SB277, which removed the personal belief exemption to school immunization requirements, making medical exemptions the only valid way to send an unvaccinated child in the affected categories to school. Naturally, vaccine-hesitant parents opposed the legislation. After their efforts failed in the legislature, they turned to the courts, raising arguments old and new. To date, opponents have filed five lawsuits against the new California law, all of which have failed. This Article explains why courts in the United States, which have consistently upheld school immunization requirements, are correct to do so. These requirements are supported by strong policy reasons and serve a compelling interest, since they dramatically reduce the risk of outbreaks of potentially deadly diseases. These mandates fit with our basic principles of state police power, reasonable limits on individual rights, and protecting children. They are also supported by over a hundred years of jurisprudence. Using the opponents' arguments to identify the strongest claims against SB277, the Article explains why those arguments—including claims based in the First Amendment, in parental rights, and in the right to education—cannot stand.

Journal of Experimental Medicine

Published December 3, 2018

<u>Vaccines: An achievement of civilization, a human right, our health insurance for the future</u>

Rino Rappuoli, Angela Santoni, Alberto Mantovani *Abstract*

Vaccines have made a key, cost-effective contribution to the prolongation of life expectancy and quality. Here we summarize challenges facing vaccinology and immunology at the level of society, scientific innovation, and technology in a global health perspective. We argue that vaccines represent a safety belt and life insurance for humankind. "...but there was as yet no cause for the sort of alarm that had been displayed by parents, 'justifiably enough,' twenty-eight years earlier, during the largest outbreak of the disease ever reported—the 1916 polio epidemic in the northeastern United States, when there had been more than 27,000 cases, with 6,000 deaths. In Newark there had been 1,360 cases and 363 deaths. Now even in a year with an average number of cases..." (Roth, 2010).

* * * * *

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 8 Dec 2018 [No new, unique, relevant content]

BBC

http://www.bbc.co.uk/ Accessed 8 Dec 2018 [No new, unique, relevant content]

The Economist

http://www.economist.com/ Accessed 8 Dec 2018 [No new, unique, relevant content]

Financial Times

http://www.ft.com/home/uk Accessed 8 Dec 2018

EU warns of bioterror and disease risk as vaccination rates fall

6 December 2018

The EU will face threats from disease epidemics to bioterrorism if it fails to halt anti-vaccination trends driven in part by anti-establishment political movements, the bloc's health commissioner has warned...

Forbes

http://www.forbes.com/ Accessed 8 Dec 2018 [No new, unique, relevant content]

Foreign Affairs

http://www.foreignaffairs.com/ Accessed 8 Dec 2018 [No new, unique, relevant content]

Foreign Policy

http://foreignpolicy.com/ Accessed 8 Dec 2018 [No new, unique, relevant content]

The Guardian

http://www.guardiannews.com/ Accessed 8 Dec 2018 The Observer Interview

<u>Peter Hotez: 'What happens when the anti-vaccine movement moves into India?'</u>
Andrew Anthony

The American scientist, whose new book explains why vaccines didn't cause his daughter's autism, on why conspiracy theorists need to be challenged

New Yorker

http://www.newyorker.com/ Accessed 8 Dec 2018 [No new, unique, relevant content]

New York Times

http://www.nytimes.com/ Accessed 8 Dec 2018 Africa

Ebola Spreads to Major Congo City as Vaccines a Concern

By The Associated Press

Dec. 7, 2018 DAKAR, Senegal — The second-largest Ebola outbreak in history has spread to a major city in eastern Congo, as health experts worry whether the stock of an experimental vaccine will stand up to the demands of an epidemic with no end in sight.

Butembo, with more than 1 million residents, is now reporting cases of the deadly hemorrhagic fever. That complicates Ebola containment work already challenged by rebel attacks elsewhere that have made tracking the virus almost impossible in some isolated villages. "We are very concerned by the epidemiological situation in the Butembo area," said John Johnson, project coordinator with Medecins Sans Frontieres in the city. New cases are increasing quickly in the eastern suburbs and outlying, isolated districts, the medical charity said...

Europe

WHO Says It Can Fight Ebola Outbreak Despite US Withdrawal

Dec. 3, 2018

The head of the World Health Organization said Monday it can fight the deadly Ebola outbreak in Congo despite the withdrawal of the U.S. Centers for Disease Control and Prevention, insisting: "We can cover it."

Wall Street Journal

http://online.wsj.com/home-page? wsjregion=na,us& homepage=/home/us Accessed 8 Dec 2018 [No new, unique, relevant content]

Washington Post

http://www.washingtonpost.com/ Accessed 8 Dec 2018 [No new, unique, relevant content]

* * * *

Think Tanks et al

Brookings

http://www.brookings.edu/ Accessed 8 Dec 2018 [No new relevant content]

Center for Global Development

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

Accessed 8 Dec 2018

[No new relevant content]

CSIS

https://www.csis.org/ Accessed 8 Dec 2018 [No new relevant content]

Council on Foreign Relations

http://www.cfr.org/ Accessed 8 Dec 2018 [No new relevant content]

Vaccines and Global Health: The Week in Review is a service of the Center for Vaccine Ethics and Policy (<u>CVEP</u>) 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 <u>GE2P2 Global Foundation</u> – 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 <u>Bill & Melinda Gates Foundation</u>; <u>Aeras</u>; <u>PATH</u>, and industry resource members Janssen/J&J, Pfizer, Sanofi Pasteur U.S., Takeda, Moderna Therapeutics (list in formation), and the Developing Countries Vaccine Manufacturers Network (<u>DCVMN</u>).

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.

* * * *

* * * * *