

Vaccines and Global Health: The Week in Review 10 September 2016 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 http://centerforvaccineethicsandpolicy.wordpress.com/. This blog allows full-text searching of over 8,000 entries.

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

Contents [click on link below to move to associated content]

A. Zika; Ebola/EVD; Polio; MERS-Cov; Yellow Fever

B. WHO; CDC

C. Announcements/Milestones/Perspectives

D. Reports/Research/Analysis

E. Journal Watch

F. Media Watch

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Zika virus [to 10 September 2016] *Public Health Emergency of International Concern (PHEIC)*http://www.who.int/emergencies/zika-virus/en/

Zika situation report – 8 September 2016

Full report: http://www.who.int/emergencies/zika-virus/situation-report/8-september-2016/en/ Key Updates

- :: Countries and territories reporting mosquito-borne Zika virus infections for the first time in the past week:
 - ...None
- ...Malaysia has reported one locally acquired mosquito-borne Zika infection in the past week. Prior to this, the only evidence of Zika in Malaysia had been a scientific publication that had reported a case of Zika infection identified in Germany in an individual with travel history to Malaysia.
- :: Countries and territories reporting microcephaly and other central nervous system (CNS) malformations potentially associated with Zika virus infection for the first time in the past week: ...None
- :: Countries and territories reporting Guillain-Barré syndrome (GBS) cases associated with Zika virus infection for the first time in the past week:
 - ...None

The Netherlands reported evidence of person-to-person transmission of Zika virus (probably via a sexual route) for the first time in the past week.

- :: Operational updates from the WHO Regional Office for the Americas:
- ...WHO convened a workshop in Barbados on clinical management of neurological complications.
- ...A technical mission to Brazil by WHO/PAHO for laboratory assessment and strengthening of Zika diagnostic capacity of State laboratories was completed in August.
- ...WHO facilitated two meetings in Panama for updating the strategic plan for vector surveillance and control.
- ...WHO/PAHO carried out missions to Colombia and El Salvador to organize and help launch "Mosquito Awareness Week".
- ...In Haiti, WHO and the Ministry of Public Health and Population's Division of Epidemiology, Laboratory and Research (DELR) held three train-the-trainer workshops on epidemiological surveillance of Zika and its complications in August.
- :: The results from the sequencing analysis of Zika virus cases in Singapore indicate that the virus belongs to the Asian lineage and likely evolved from the strain that was previously circulating in Southeast Asia. The recent cases in Singapore do not appear to be the result of imported virus from South America.
- :: The 2016 Summer Paralympic Games opened in Rio de Janeiro, Brazil, on 7 September. WHO continues to provide technical support to the Ministry of Health to ensure the 2016 Summer Paralympic Games are as safe as possible for all athletes, volunteers, visitors and residents. There is a low, but not zero, risk of Zika transmission in this setting. All persons should continue to follow guidance on avoiding Zika infection.
- :: The fourth meeting of the Emergency Committee was held on 1 September 2016. Having considered the evidence presented, the Committee agreed that due to continuing geographic expansion and considerable gaps in understanding of the virus and its consequences, Zika virus infection and its associated congenital and other neurological disorders continues to be a Public Health Emergency of International Concern.

- :: Based on a systematic review of the literature, WHO has concluded that Zika virus infection during pregnancy is a cause of congenital brain abnormalities, including microcephaly, and that Zika virus is a trigger of GBS.
- :: Revised guidance on the prevention of sexual transmission was published on 6 September 2016.

Zika Open [to 10 September 2016] [Bulletin of the World Health Organization] :: <u>All papers available here</u>
No new papers identified.

WHO

<u>Updated guidance on prevention of sexual transmission of Zika virus</u>

6 September 2016 – The interim guidance on prevention of sexual transmission of Zika virus has been updated with new evidence and advice. The primary transmission route of Zika virus is via the Aedes mosquito, however mounting evidence shows that sexual transmission of Zika virus is possible and more common than previously assumed. This is of concern due to an association between the Zika virus and adverse pregnancy outcomes.

Read the guidance

Information for travellers

Updated 6 September 2016

Information for health authorities

Updated 6 September 2016

Fact sheet: Zika virus

Updated 6 September 2016

Q&A: Zika virus

Updated 6 September 2016

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EBOLA/EVD [to 10 September 2016]

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

"Threat to international peace and security" (UN Security Council)

[Editor's Note:

We note that the Ebola tab - which had been listed along with Zika, Yellow Fever, MERS CoV and other emergencies - has been removed from the WHO "home page. We deduce that WHO has suspended issuance of new Situation Reports after resuming them for several weekly cycles. The most recent report posted is <u>EBOLA VIRUS DISEASE - Situation Report - 10 JUNE</u> 2016]

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POLIO [to 10 September 2016]

Public Health Emergency of International Concern (PHEIC)

Please see the extended excerpts from the IMB's 13th Report below in the "Reports..." section.

Polio this week as of 7 September 2016

- : In Nigeria, one new wild poliovirus type 1 (WPV1) case has been reported, from Borno state, following confirmation of two cases in August. Regional outbreak response across northeastern Nigeria and the Lake Chad sub-region is continuing within the broader humanitarian emergency context. Detection of new cases at this point is not unexpected or unusual, particularly as surveillance is being strengthened (including by conducting retrospective acute flaccid paralysis case searches).
- :: The polio outbreak has been declared a national public health emergency by the Government of Nigeria and a regional public health emergency by the Governments of the Lake Chad subregion, to ensure all-of-government, all-of-society approaches to the outbreak response. See 'Nigeria' section below for more.
- : The Global Polio Eradication Initiative has launched an emergency appeal to respond to the polio outbreak across the region. Against the planned outbreak response budget of US\$116 million, a critical funding gap of US\$33 million must be urgently filled. More. [excerpt from appeal]

KEY FACTS

- :: Wild poliovirus type 1 outbreak in Nigeria: 2 cases
- :: High risk of poliovirus spread in the Lake Chad area
- :: Ongoing Polio Outbreak Response in Northern Nigeria and Lake Chad area implemented as part of the broader humanitarian response effort
- :: WHO has declared Northern Nigeria a Grade 3 Humanitarian Emergency
- :: UNICEF has activated its Level 3 Corporate Emergency Procedure for North East Nigeria
- :: Budget requirements: US116 million
- :: Funding gap: US\$33 million

:: Selected Country Updates [excerpts]

Pakistan

:: One new case of wild poliovirus type 1 (WPV1) was reported in the past week, from South Waziristan, Federally Administered Tribal Areas (FATA), with onset of paralysis on 27 July. It is the most recent case in the country, bringing the total number of WPV1 cases for 2016 to 14.

Nigeria

- :: One new case of wild poliovirus type 1 (WPV1) was reported in the past week, from Monguno Local Government Area (LGA), Borno state, with onset of paralysis on 6 August. It is the most recent case in country and brings the total number of WPV1 cases for 2016 to three.
- :: Detection of new cases at this point is not unexpected or unusual, particularly as surveillance is being strengthened (including by conducting retrospective acute flaccid paralysis case searches).

- :: A full case investigation of the third case is ongoing, however the child had onset of paralysis on 6 August and was detected in an accessible internally-displaced persons camp in Monguno LGA. The child's family had originally arrived from Marte LGA (as had the family of the case from Jere LGA reported in August).
- :: An emergency regional outbreak response is continuing under the guidance of the Emergency Operations Committee, led by the Government of Nigeria and with support from WHO and GPEI partners, including with inactivated polio vaccine (IPV). The outbreak response is being coordinated with neighbouring countries and in the broader humanitarian emergency response context affecting the region. Similar approaches to outbreak response were successfully implemented in previous years in the Middle East and the Horn of Africa.

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Yellow Fever [to 10 September 2016] http://www.who.int/emergencies/yellow-fever/en/

<u>Yellow Fever - Situation Report - 9 September 2016</u>

Full Report:

http://apps.who.int/iris/bitstream/10665/250077/1/yellowfeversitrep9Sep16-eng.pdf?ua=1 Key updates

Angola epidemiological update (as of 1 September):

- :: There have been no new confirmed cases since 23 June.
- :: Phase I of the preventive vaccination campaign in Angola was completed and, as of 1 September, 2,807,628 people had been vaccinated. Phase II of the campaign is being prepared and will target more than three million people in 12 provinces.

Democratic Republic of The Congo (DRC) epidemiological update (as of 8 September):

- :: There have been no confirmed cases related to the current outbreak since 12 July.
- :: The first notified case reported in Bominenge Health Zone in Sud Ubangi province is still under investigation. A second case was notified from Budjala Health Zone, a different zone within Sud Ubangui province, in the week to 8 September and is being investigated.
- :: The pre-emptive vaccination campaign in DRC has concluded. The preliminary results indicate that the administrative immunization coverage reached 103.1% in Kinshasa, 101% in Kasai Central, 98.3% in Kongo Central, 101% in Kasai, 101% in Kwango, and 100.8% in Lualaba. Independent monitoring assessed that vaccination coverage is 98.2% in Kinshasa.

Uganda declared the end of their yellow fever outbreak on 6 September 2016. This outbreak was not linked to the outbreak in Angola and DRC.

Updated strategy for the Elimination of Yellow fever Epidemics (EYE)

Partners' meeting

Date: 12 September 2016 Place: Geneva, Switzerland

Purpose

Bring together partners involved in development and implementation of the updated strategy for the Elimination of Yellow fever Epidemics.

Objectives

- :: Update partners on objectives and strategic axis of the new strategy.
- :: Engage with partners on development and implementation.
- :: Define immediate and long-term steps to support the strategy.

Preliminary agenda pdf, 380kb

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MERS-CoV [to 10 September 2016] http://www.who.int/emergencies/mers-cov/en/

WHO statement on the tenth meeting of the IHR Emergency Committee regarding MERS

3 September 2015 [Editor's text bolding]

The tenth meeting of the Emergency Committee (EC) convened by the Director-General under the International Health Regulations (2005) (IHR 2005) regarding the Middle East respiratory syndrome 1 was held by teleconference on 2 September 2015, from 1300 to 1620 Central European Summer Time (UTC +2). During the meeting the WHO Secretariat provided an update to the Committee on epidemiological and scientific developments, including recent cases and transmission patterns in the Kingdom of Saudi Arabia (KSA), Jordan and the United Arab Emirates. The Secretariat also provided current risk assessments with regard to these events, and information on control and prevention measures...

...Members of the EC agreed that the situation still does not constitute a Public Health Emergency of International Concern (PHEIC). At the same time, they emphasized that they have a heightened sense of concern about the overall MERS situation. Although it has been three years since the emergence of MERS in humans was recognized, the global community remains within the grip of this emerging infectious disease. There is continued virus transmission from camels to humans in some countries and continued instances of human-to-human transmission in health care settings. Nosocomial outbreaks have most often been associated with exposure to persons with unrecognized MERS infection. The major factors contributing to the ongoing situation are insufficient awareness about the urgent dangers posed by this virus, insufficient engagement by all relevant sectors, and insufficient implementation of scalable infection control measures, especially in health care settings such as emergency departments. The Committee recognizes that tremendous efforts have been made and some progress has been achieved in these areas. However, the Committee also notes that the progress is not yet sufficient to control this threat and until this is achieved, individual countries and the global community will remain at significant risk for further outbreaks.

Moreover, the current outbreak is occurring close to the start of the Hajj and many pilgrims will return to countries with weak surveillance and health systems. The recent outbreak in the Republic of Korea demonstrated that when the MERS virus appears in a new setting, there is great potential for widespread transmission and severe disruption to the health system and to society....

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WHO & Regional Offices [to 10 September 2016]

WHO and partners battle multiple disease outbreaks in South Sudan

9 September 2016

Infectious diseases continue to pose a major public health threat in South Sudan. Adding to the chronic burden of disease, regular outbreaks further threaten people's health.

In a conflict setting, WHO and partners are responding to multiple outbreaks including cholera, malaria, measles, suspected hemorrhagic fever, and kala-azar.

"In spite of the insecurity, WHO is taking every opportunity to ensure that we reach the people with health care services to protect them at this time when the health system has crumbled," says Dr, Abdulmumini Usman, WHO Representative to South Sudan...

WHO-IVB: Call for nomination for experts to serve on a Strategic Advisory Group of Experts (SAGE) on Immunization working group on Pneumococcal Conjugate Vaccine (PCV)

5 September 2016

Deadline for application: 30 September 2016

Highlights

WHO certifies Sri Lanka malaria-free

September 2016 – In a remarkable public health achievement, Sri Lanka was certified today by WHO on having eliminated malaria, a life-threatening disease which long affected the island country.

:: WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO:

:: <u>DRC vaccinates more than 10 million people in Africa's largest yellow fever vaccination campaign</u>

BRAZZAVILLE, 6 September 2016 – The largest emergency vaccination campaign against yellow fever ever attempted in Africa, came to an end on 5 September 2016 with more than 10.6 million people in the Democratic Republic of Congo (DRC) vaccinated against the lethal disease.

WHO Region of the Americas PAHO

:: New PAHO publication brings together strategies for suicide prevention in the Americas (09/09/2016)

WHO South-East Asia Region SEARO

- :: South-East Asia countries to set up fund for health emergencies preparedness
- 9 September 2016
- :: Focus on migrant health: WHO 8 September 2016

WHO European Region EURO

:: Preventing alcohol exposure in pregnancy: examples from Member States 08-09-2016

- :: WHO governing body for the European Region convenes with eight strategic proposals on the agenda 08-09-2016
- :: <u>Evidence-informed policy-making in the spotlight in new edition of Public Health Panorama</u> 07-09-2016
- :: WHO Europe launches new action plan for noncommunicable diseases, appeals for urgent joint policy action to achieve global goals and targets 06-09-2016

WHO Eastern Mediterranean Region EMRO

- :: <u>Millions of children in Pakistan reached with polio vaccine thanks to United Arab Emirates campaign</u> 7 September 2016
- :: WHO supports training of Somali health workers to scale up the cholera outbreak response 4 September 2016

WHO Western Pacific Region

No new announcements identified.

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CDC/ACIP [to 10 September 2016] http://www.cdc.gov/media/index.html https://www.cdc.gov/vaccines/acip/

MMWR Weekly September 9, 2016 / No. 35

:: <u>Cessation of Trivalent Oral Poliovirus Vaccine and Introduction of Inactivated Poliovirus Vaccine — Worldwide, 2016</u>

:: <u>Outbreak of Serogroup C Meningococcal Disease Primarily Affecting Men Who Have Sex with</u> Men — Southern California, 2016

Register for upcoming October ACIP meeting

October 19-20, 2016 Deadline for registration:

:: Non-US Citizens: September 28, 2016

:: US Citizens: October 10, 2016

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Announcements/Milestones/Perspectives

Industry Watch [to 10 September 2016]

:: <u>Takeda Initiates Global Phase 3 Clinical Trial (TIDES) of Dengue Vaccine</u>
<u>Candidate (TAK-003)</u>

Study to evaluate vaccine protection against all four strains of dengue virus, regardless of previous exposure
September 07, 2016

OSAKA, Japan--(BUSINESS WIRE)--Takeda Pharmaceutical Company Limited today announced that it has vaccinated the first subject in the Tetravalent Immunization against Dengue Efficacy Study (TIDES), a Phase 3 double-blind, randomized and placebo-controlled trial of its live-attenuated tetravalent dengue vaccine candidate (TAK-003).

TIDES will enroll approximately 20,000 healthy children between the ages of four and 16 years living in dengue-endemic countries in Latin America and Asia. The study will evaluate the efficacy of the vaccine candidate to protect subjects against symptomatic dengue fever caused by any of the four dengue virus serotypes, regardless of age and whether the individual has previously been exposed to the virus. The study will also evaluate vaccine safety and immunogenicity and will involve two doses of the vaccine candidate or placebo administered 90 days apart.1 ...

:: <u>U.S. Biomedical Advanced Research and Development Authority (BARDA) Awards</u> Protein Sciences Multi-Million Dollar Contract for Pandemic Preparedness

MERIDEN, Conn., Sept. 7, 2016 /PRNewswire/ -- Protein Sciences Corporation announced today that the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services, has awarded the Company a contract that is part of the Authority's medical countermeasures against pandemic influenza and influenza strains with pandemic potential (contract number HHSO100201600005I). Protein Sciences will perform the contract using its proprietary platform technology for producing vaccines that according to the Food and Drug Administration has revolutionized influenza vaccine manufacturing and stands to receive up to \$610 million through 2021 if BARDA exercises all options...

:: Gyeongbuk Kick-Starts Vaccine Industry with 'Global Vaccine Industry Forum 2016'

- More than 200 experts from industry, academia, research institutes from Korea and abroad, including IVI, in attendance
- MOU between IVI, Gyeongbuk (province), Andong (city) signed; keynote speech, presentations, discussions delivered
- Officials from global vaccine enterprises including GSK, Sanofi Pasteur, Bill & Melinda Gates Foundation invited to attend

Gyeongsangbuk-do (Gyeongbuk or North Gyeongsang Province) held the opening ceremony of the 'Gyeongbuk Global Vaccine Industry Forum 2016' at Richell Hotel in Andong on September 9 to seek to set direction and strategy for development of the vaccine industry, form a network with domestic and overseas partners, and expedite mutual exchange in order to lay the foundation to nurture the vaccine industry.

Held under the theme "Present and Future of Globalization of the Korean Vaccine Industry," the forum is taking place on September 8 - 10. The opening ceremony on September 9 was a huge success, as it brought together more than 200 vaccine experts and officials including Gyeongbuk Governor Kim Kwan-yong, Rep. Kim Kim Gwang-lim, Andong Mayor Kwon Youngse, and Jerome Kim, Director General of the International Vaccine Institute...

:: <u>DCVMN [Developing Country Vaccine Manufacturers Network] Annual General</u> Meeting

24 October 2016 to 27 October 2016 Buenos Aires / / Argentina

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IAVI – International AIDS Vaccine Initiative [to 10 September 2016]

https://www.iavi.org/ September 8, 2016

New Vaccination Strategies Successfully Coach Immune System to Make Powerful HIV-Neutralizing Antibodies

New approaches that could spur the human body to produce HIV-blocking antibodies have been successful in mice mimicking the human immune system, according to five studies published today in the research journals Cell, Immunity and Science.

The results were produced by scientists affiliated with the International AIDS Vaccine Initiative (IAVI); The Scripps Research Institute (TSRI); U.S National Institute of Health's National Institute of Allergy and Infectious Diseases (NIAID); Howard Hughes Medical Institute (HHMI); The Rockefeller University; Ragon Institute of Massachusetts General Hospital, MIT and Harvard; Boston Children's Hospital; Massachusetts Institute of Technology (MIT); Harvard Medical School (HMS); Vanderbilt University; Columbia University; Fred Hutchinson Cancer Research Center (FHCRC); Duke University School of Medicine and Kymab Ltd...

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European Medicines Agency [to 10 September 2016]

http://www.ema.europa.eu/ 07/09/2016

Fighting antimicrobial resistance globally

EMA, FDA and PMDA discuss regulatory approaches for the evaluation of new antibacterial agents

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NIH [to 10 September 2016]

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

September 8, 2016

Federal prize competition seeks innovative ideas to combat antimicrobial resistance

Contestants will vie for \$20 million in prizes to develop new innovative laboratory diagnostic tools that detect and distinguish antibiotic resistant bacteria.

NCI embraces scientific road map to achieve Cancer Moonshot goals

September 7, 2016 — Blue Ribbon Panel outlines 10 transformative approaches for accelerating progress against cancer.

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FDA [to 10 September 2016]

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

What's New for Biologics

:: Influenza Virus Vaccine for the 2016-2017 Season Posted: 9/7/2016

:: <u>Public Hearing; Request for Comments – Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products</u>

Updated to include a link to the webcast; Updated: 9/8/2016

- :: Statistical Review Afluria Quadrivalent (PDF 251KB) Posted: 9/6/2016
- :: Clinical Review Afluria Quadrivalent (PDF 587KB) Posted: 9/6/2016
- :: <u>Final Agenda: Part 15 Hearing: Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products</u> Updated: 9/6/2016

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European Vaccine Initiative [to 10 September 2016]

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

News

EVI Annual Report 2015 now available

09 September 2016

The EVI <u>2015 Annual Report</u> provides a detailed insight into all of EVI's activities, projects, important meetings etc. We hope you will find it not only enlightening, but interesting reading.

News

New publication emanating from EVI project AMA1

08 September 2016

New article published on 30 August 2016 in Malaria Journal emanating from EVI project AMA1

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Fondation Merieux [to 10 September 2016]

Mission: Contribute to global health by strengthening local capacities of developing countries to reduce the impact of infectious diseases on vulnerable populations.

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

7 September 2016, Lyon (France)

"Better Foods for Better Health" White Book: 30 global experts share the latest findings on microbiota in disease prevention and obesity

The 5th edition of the Better Foods for Better Health White Book has been published, providing new insight from 30 thought leaders from science and industry on the growing role and potential of gut microbiota to improve health.

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EDCTP [to 10 September 2016]

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.

6 September 2016

Notice of voluntary liquidation of EDCTP-EEIG (legal structure for the first EDCTP programme, 2003-2015)

The EDCTP-EEIG, the legal structure for the first EDCTP programme (2003-2015), is in liquidation (Dutch: in liquidatie). The EDCTP-EEIG was incorporated for the implementation of the activities set out in the contract signed between the EDCTP-EEIG and the European Commission. Following the successful completion of the first programme, the EDCTP-EEIG General Assembly approved on 3 June 2016 the complete liquidation of the EDCTP-EEIG legal entity and the winding up of its affairs...

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AERAS [to 10 September 2016] http://www.aeras.org/pressreleases No new digest content identified.

Gavi [to 10 September 2016] http://www.gavi.org/library/news/press-releases/ No new digest content identified

GHIT Fund [to 10 September 2016]

https://www.ghitfund.org/

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 companies, the Japanese Government and the Bill & Melinda Gates Foundation. No new digest content identified

Global Fund [to 10 September 2016]

http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country= No new digest content identified

Hilleman Laboratories [to 10 September 2016]

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

Human Vaccines Project [to 10 September 2016]

humanvaccinesproject.org
[Website in development]

PATH [to 10 September 2016] http://www.path.org/news/index.php *No new digest content identified*

UNICEF [to 10 September 2016] http://www.unicef.org/media/media_89711.html No new digest content identified

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<u>Reports/Research/Analysis/Commentary/Conferences/Meetings/Book</u> <u>Watch/Tenders</u>

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

THE 13TH REPORT OF THE INDEPENDENT MONITORING BOARD (IMB) OF THE GLOBAL POLIO ERADICATION INITIATIVE (GPEI)

August 2016 :: 28 pages

Overview

This report follows the 14th meeting of the Independent Monitoring Board (IMB) of the Global Polio Eradication Initiative (GPEI). The Report comes at a critical time. It is making an assessment of the progress of the Polio Programme with six months to go before the declared GPEI deadline. By the end of December 2016, transmission of the poliovirus should be interrupted everywhere in the world.

[Introductory Content]

THE IMB CALL FOR PEAK PERFORMANCE

When the IMB issued its previous report, it did so against a background that the Polio Programme in the two remaining endemic countries (Pakistan and Afghanistan) had the advantage of facing the last Low Season (before the GPEI deadline) with the smallest burden of poliovirus in human history. The IMB entitled its last report: *Now is the Time for Peak Performance*. This title reflected the IMB's analysis that, despite a rising tide of improving performance, the Polio Programme still had many islands of mediocrity (within countries and systemically across the programme) where sub-optimal delivery meant that the goal of stopping polio transmission in the near future remained improbable.

PROGRESS ACHIEVED BUT NOT YET PEAK PERFORMANCE

Since the last IMB report, there have been further, very substantial, improvements:

- :: the global footprint of the poliovirus is the smallest in human history
- :: the continent of Africa still has no polio endemic countries within it
- :: the Polio Programme in Pakistan is achieving a high level of performance overall and in this respect is transformed from its position three years ago
- : the establishment of an Emergency Operations Centre and changes of GPEI personnel in Afghanistan have led to a jump up in the level of performance
- :: more female health workers are making a difference, meeting mothers on doorsteps that have not been reached before
- :: within the GPEI, the quality of working relationships, the effectiveness of governance structures, and the management of big strategic changes is much better than previously

However, the IMB is quite clear that the Polio Programme has not yet reached peak performance, and this is disappointing. With six months to go, it must do so if the goal of ending polio transmission by the end of 2016 is to be realized. This challenge has become more complex since the last IMB report. It is no longer the polio Low Season in Pakistan and Afghanistan: the High Season is upon those countries' programmes. There has been a planned

global strategic switch in the type of oral polio vaccine used in immunization campaigns, with a resulting heightened risk of outbreaks of vaccine-derived viruses (these are also capable of causing paralysis). There is a world shortage of the inactivated polio vaccine (administered by injection). This vaccine should be acting as vital adjunct to boosting children's immunity, particularly in communities where access is only being achieved intermittently but there is not enough of it to go round...

...VULNERABLE AREAS: REINSTATEMENT OF THE RED LIST

The Polio Programme is entering uncharted waters. The GPEI promise to interrupt polio transmission everywhere in the world by the end of 2016 is only six months from its intended delivery. No one can be sure what it will take to remove every last vestige of the disease from the planet. This is in circumstances where there are many pockets of low immunity in some of the most marginalized populations of the world, and where ongoing use of the oral vaccine can release virus that causes paralytic polio. The only modern parallel is the smallpox eradication programme: a different disease, in a different time.

Taken together, a weakness in effective surveillance, a heightened risk of vaccine-derived poliovirus, and variable performance of routine immunization demonstrate a potentially hazardous combination for the programme. There are many parts of the world that are in just this situation. In an earlier report, the IMB urged the GPEI to establish a publicly prominent list of vulnerable countries and call it *The Red List*. This was accepted and ran for a short time but then sank from view, thereby losing the power and transparency of the concept.

The IMB believes that the concept of a Red List should be re-established. The Polio Programme should not be waiting for the predictable to happen, it should be advocating many more preventive immunization activities - both through routine immunization and IPV and OPV campaigns...

...SUMMARY OF THE IMB'S MAJOR CONCERNS

- 1 The level of joint working between the governments of Pakistan and Afghanistan is still falling below that required to interrupt polio transmission in the border areas and from the large reservoirs of infection that span the two countries.
- 2 The low degree of political engagement in Northern Sindh is a major barrier to eliminating polio from that part of Pakistan.
- 3 The Polio Programme in many parts of Karachi has been chronically underperforming.
- 4 The number of missed children in the inaccessible eastern area of Afghanistan has gone up from 26,000 in March 2016 to 130,000 in May 2016.
- 5 In the southern region of Afghanistan, the proportion of missed children has hardly changed in two years and the proportion of refusals continues to be the highest of all polio-affected countries (and has been stagnant for four years).
- 6 The Afghanistan Polio Programme is continuing to use male vaccinators from outside despite it being well known that matching of a vaccinator's characteristics with the religious and cultural

composition of the local population is vital to acceptance; the failure of the GPEI to scale up within Afghanistan the use of local female health workers is a serious failing.

- 7 The performance of the Non-Governmental Organizations (NGOs) that deliver basic health services through a contract with the Afghanistan Government is patchy and accountability and performance management arrangements are far too weak. The relationship between this model of service delivery and the requirements to deliver a high-performing Polio Programme are not at all clear.
- 8 There seems to be either a lack of openness or a lack of situational awareness in the Afghanistan Polio Programme that, taken together with the other concerns, suggests an inappropriate reliance on ending transmission in Pakistan and a "good enough" performance philosophy.
- 9 The surveillance functions of the Polio Programme have been given much less emphasis than the immunization activities; as a result, surveillance is not fit for the purpose of addressing the challenges that the Programme now faces.
- 10 A poliovirus was discovered in Borno that had been circulating undetected for nearly two years, whilst half a million children have been missed. This, and multiple IMB sources speaking of a waning commitment in Nigeria, means that the Polio Programme in this country is not yet fully resilient against a re-emergence of poliovirus.
- 11 It is alarming that the Polio Programme has failed to meet the standards for dealing with outbreaks of vaccine-derived polioviruses (particularly so in Guinea and Madagascar). Slow reactions and delayed decision-making when viruses are discovered could be the Polio Programme's downfall unless it learns quickly from these dysfunctions.
- 12 The apparent intractability of a situation, in a \$1billion a year programme, in which an area of 1.5 Km in Eastern Afghanistan with a population of 1000 people has been responsible for 20% of the entire world's polio cases in 2016 is extraordinary; the area has been inaccessible to polio immunization teams for four years.
- 13 The list of countries with low levels of immunity to polio and inadequate surveillance is lengthy; the Polio Programme is not gaining from the beneficial pressures that flow from maintaining a publicly prominent Red List (as previously).
- 14 The Polio Programme has a wide range of innovative quantitative social data but their use is not mainstreamed at all levels, it needs qualitative data; as a result striking findings on parental and community attitudes are not being used to generate definitive and transformational improvement in performance.
- 15 The outbreak of wild poliovirus in Bannu, Pakistan in April and May was a surprise; it seemed to be well protected. The Polio Programmes in Pakistan, Afghanistan, and Nigeria need to have more structured systems of soft intelligence to identify places where official monitoring data shows a "too good to be true" situation; the Programme cannot afford "more Bannus."

16 The global oral polio vaccine switch will have left many countries with large supplies of redundant trivalent vaccine. There is a risk that an ill-informed local decision maker, mindful of waste and costs, might deploy the trivalent vaccine in immunization campaigns; it is not clear whether the GPEI has eliminated this source of risk.

17 After polio eradication has been officially certified, the oral polio vaccine will still be in use. At this point the GPEI will have been disbanded. It is not clear that there is a plan for this eventuality.

RECOMMENDATIONS

- 1 A very high-level GPEI leader should be appointed to strengthen the cohesiveness of the joint working of the Pakistan and Afghanistan governments. The person appointed should have the seniority and personal qualities to operate effectively in this role and should be perceived as politically neutral. The person should work out of Geneva, not the WHO Eastern Mediterranean Office (EMRO). In post by mid-September 2016.
- 2 The WHO Eastern Mediterranean Office (EMRO) should appoint a senior female official to its Polio Programme team. She should be charged with rapidly strengthening the role and capacity of female workers in the successful delivery of polio immunization (and in due course routine immunization). She should give immediate attention to removing the barriers to progress in Afghanistan. In post by end September 2016.
- 3 CDC Atlanta should facilitate the Polio Programmes in Pakistan and Afghanistan in undertaking a full process mapping of Acute Flaccid Paralysis (AFP) reporting and assessment. This should involve evaluating the shortfalls in quality in each step of the process and identify measures to strengthen them. It should be well informed with detailed local knowledge of the current situation and sufficiently granular to take account of context-specific aspects of the process that will vary from place to place. An action plan, informed by this work, should be immediately implemented in Karachi, as a pilot, and its impact monitored. Completed by end-September 2016.
- 4 The GPEI should introduce a system of financial incentives for reporting Acute Flaccid Paralysis (AFP) cases in Pakistan. To this end, any healthcare worker who reports a case should be paid, with a higher payment being given for confirmed cases. Safeguards should be built in for independent validation to prevent unfair manipulation of the system. The scheme should be piloted in Karachi where awareness of frontline healthcare staff is very low. The urgent advice of public health officials in the Egyptian government should be sought in designing the scheme. Operational by end September 2016.
- 5 UNICEF should specially commission rapid qualitative data gathering to provide an in-depth understanding of the reasons for poor performance on social indicators in communities within the Pakistan-Afghanistan Core Reservoirs. Report of the findings to be with the IMB by end-September 2016.
- 6 Each Emergency Operations Centre (EOC) both national and regional –should designate one team member to regularly gather soft intelligence from the field to identify situations where monitoring data are providing a falsely positive picture. This person should be someone who is completely trusted by field workers, who can speak to him or her on condition of anonymity,

and who can feed back synthesized information to the EOC team; the information should be used for learning and improvement and on no account for retribution against any fieldworker. Arrangements in place by end-September 2016.

7 The contractual arrangements governing the accountability and performance management of the Non-Governmental Organizations delivering basic health services in Afghanistan should be redrawn to address chronic underperformance and strengthen alignment with polio activities. Redesigned accountability and performance management arrangements in place by end-October 2016.

- 8 A publicly prominent Red List of countries and areas vulnerable to polio transmission should be re- established and more targeted, preventive immunization activities should be funded and implemented. Red List to be posted by end-September 2016.
- 9 The process of implementing the GPEI standards for responding to outbreaks should be urgently reviewed at high level. This should include an open and honest assessment of the poor response to recent outbreaks, notably in Guinea. It should involve a thorough examination of the working relationships and decision-making between the headquarters of the United Nations GPEI Partners and their Regional and Country Offices. A senior independent person would be best placed to do this. Lessons learned report to be ready by end October 2016.
- 10 The GPEI leadership should make an intervention to urgently engage with the political leadership in Northern Sindh to establish a clear commitment and ownership of the goals of the Polio Programme. This should be done in consultation with the Pakistan Government and the Polio Programme leadership in this part of Pakistan. Political engagement secured by end-September 2016.
- 11 The GPEI should urgently review options for innovative approaches to environmental sampling in areas without substantial sewage systems. Environmental sampling programme commenced in FATA by early November 2016.
- 12 Nigeria's Presidential Task Force should reconvene—and the Executive Governors of each of the states should publicly reconfirm their commitment to the actions agreed in the Abuja Commitment. By end of September 2016.

Journal Watch

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

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

American Journal of Infection Control

September 2016 Volume 44, Issue 9, p963-1082, e145-e166 http://www.ajicjournal.org/current [Reviewed earlier]

American Journal of Preventive Medicine

September 2016 Volume 51, Issue 3, p281-410, e57-e90 http://www.ajpmonline.org/current [Reviewed earlier]

American Journal of Public Health

Volume 106, Issue 9 (September 2016) http://ajph.aphapublications.org/toc/ajph/current [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

September 2016; 95 (3) http://www.ajtmh.org/content/current [Reviewed earlier]

Annals of Internal Medicine

6 September 2016, Vol. 165. No. 5 http://annals.org/issue.aspx
Original Research

The Anticipated Clinical and Economic Effects of 90–90–90 in South Africa

Rochelle P. Walensky, MD, MPH; Ethan D. Borre, BA; Linda-Gail Bekker, MD, PhD; Stephen C. Resch, PhD; Emily P. Hyle, MD, SM; Robin Wood, MMed, DSc (Med); Milton C. Weinstein, PhD; Andrea L. Ciaranello, MD, MPH; Kenneth A. Freedberg, MD, MSc; and A. David Paltiel, MBA, PhD

Abstract

Background: The Joint United Nations Programme on HIV/AIDS (UNAIDS) 90–90–90 global treatment target aims to achieve 73% virologic suppression among HIV-infected persons worldwide by 2020.

Objective: To estimate the clinical and economic value of reaching this ambitious goal in South Africa, by using a microsimulation model of HIV detection, disease, and treatment.

Design: Modeling of the "current pace" strategy, which simulates existing scale-up efforts and gradual increases in overall virologic suppression from 24% to 36% in 5 years, and the UNAIDS target strategy, which simulates 73% virologic suppression in 5 years.

Data Sources: Published estimates and South African survey data on HIV transmission rates (0.16 to 9.03 per 100 person-years), HIV-specific age-stratified fertility rates (1.0 to 9.1 per 100 person-years), and costs of care (\$11 to \$31 per month for antiretroviral therapy and \$20 to \$157 per month for routine care).

Target Population: South African HIV-infected population, including incident infections over the next 10 years.

Perspective: Modified societal perspective, excluding time and productivity costs.

Time Horizon: 5 and 10 years.

Intervention: Aggressive HIV case detection, efficient linkage to care, rapid treatment scaleup, and adherence and retention interventions toward the UNAIDS target strategy.

Outcome Measures: HIV transmissions, deaths, years of life saved, maternal orphans, costs (2014 U.S. dollars), and cost-effectiveness.

Results of Base-Case Analysis: Compared with the current pace strategy, over 5 years the UNAIDS target strategy would avert 873 000 HIV transmissions, 1 174 000 deaths, and 726 000 maternal orphans while saving 3 002 000 life-years; over 10 years, it would avert 2 051 000 HIV transmissions, 2 478 000 deaths, and 1 689 000 maternal orphans while saving 13 340 000 life-years. The additional budget required for the UNAIDS target strategy would be \$7.965 billion over 5 years and \$15.979 billion over 10 years, yielding an incremental cost-effectiveness ratio of \$2720 and \$1260 per year of life saved, respectively.

Results of Sensitivity Analysis: Outcomes generally varied less than 20% from base-case outcomes when key input parameters were varied within plausible ranges.

Limitation: Several pathways may lead to 73% overall virologic suppression; these were examined in sensitivity analyses.

Conclusion: Reaching the 90–90–90 HIV suppression target would be costly but very effective and cost-effective in South Africa. Global health policymakers should mobilize the political and economic support to realize this target.

Primary Funding Source: National Institutes of Health and the Steve and Deborah Gorlin MGH Research Scholars Award.

BMC Cost Effectiveness and Resource Allocation

http://resource-allocation.biomedcentral.com/ (Accessed 10 September 2016) [No new content]

BMC Health Services Research

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

(Accessed 10 September 2016)

Research article

<u>Charting health system reconstruction in post-war Liberia: a comparison of rural vs. remote</u> healthcare utilization

Katherine Kentoffio, John D. Kraemer, Thomas Griffiths, Avi Kenny, Rajesh Panjabi, G. Andrew Sechler, Stephen Selinsky and Mark J. Siedner

BMC Health Services Research 2016 16:478

Published on: 7 September 2016

Abstract

Background

Despite a growing global emphasis on universal healthcare, access to basic primary care for remote populations in post-conflict countries remains a challenge. To better understand health sector recovery in post-conflict Liberia, this paper seeks to evaluate changes in utilization of health services among rural populations across a 5-year time span.

Methods

We assessed trends in healthcare utilization among the national rural population using the Liberian Demographic and Health Survey (DHS) from 2007 and 2013. We compared these results to results obtained from a two-staged cluster survey in 2012 in the district of Konobo, Liberia, to assess for differential health utilization in an isolated, remote region. Our primary outcomes of interest were maternal and child health service care seeking and utilization. Results

Most child and maternal health indicators improved in the DHS rural sub-sample from 2007 to 2013. However, this progress was not reflected in the remote Konobo population. A lower proportion of women received 4+ antenatal care visits (AOR 0.28, P < 0.001) or any postnatal care (AOR 0.25, P <0.001) in Konobo as compared to the 2013 DHS. Similarly, a lower proportion of children received professional care for common childhood illnesses, including acute respiratory infection (9 % vs. 52 %, P < 0.001) or diarrhea (11 % vs. 46 %, P < 0.001). Conclusions

Our data suggest that, despite the demonstrable success of post-war rehabilitation in rural regions, particularly remote populations in Liberia remain at disproportionate risk for limited access to basic health services. As a renewed effort is placed on health systems reconstruction in the wake of the Ebola-epidemic, a specific focus on solutions to reach isolated populations will be necessary in order to ensure extension of coverage to remote regions such as Konobo.

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 10 September 2016) [No new relevant content identified]

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content (Accessed 10 September 2016) Debate

Research involving adults lacking capacity to consent: the impact of research regulation on 'evidence biased' medicine

Victoria Shepherd

Published on: 8 September 2016

Abstract Background

Society is failing in its moral obligation to improve the standard of healthcare provided to vulnerable populations, such as people who lack decision making capacity, by a misguided paternalism that seeks to protect them by excluding them from medical research. Uncertainties surround the basis on which decisions about research participation is made under dual regulatory regimes, which adds further complexity. Vulnerable individuals' exclusion from research as a result of such regulation risks condemning such populations to poor quality care as a result of 'evidence biased' medicine.

Main Text

This paper explores the research regulation provisions for proxy decision making for those unable to provide informed consent for themselves, and the subsequent legal and practical difficulties for decision-makers. There are two separate regulatory regimes governing research

involving adults who lack capacity to consent in England and Wales. The Mental Capacity Act 2005 governs how incapacitated adults can be involved in research, however clinical trials of medicinal products are separately regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004. There are significant differences under these dual regimes in the provisions for those lacking capacity to participate in medical research. The level of risk permitted differs, with a greater requirement for justification for participation in a clinical trial than other types of research. Who acts as proxy decision maker, how much information is provided to the person lacking capacity, and whether they retain the power of veto also significantly differs. Conclusion

The development of two separate regulatory regimes has resulted in significant differences between the provisions for clinical trials and other forms of research, and from usual medical practice. The resulting uncertainty has reinforced the tendency of those approving and conducting research to exclude adults lacking capacity to avoid difficult decisions about seeking consent for their participation. Future developments, such as the incoming EU Regulations, may address some of these differences, however the justification and level of risk permitted requires review to ensure that requirements are appropriate and proportionate to the burdens and risks for the individual, and also to the benefits for the wider population represented.

BMC Medicine

http://www.biomedcentral.com/bmcmed/content (Accessed 10 September 2016) Commentary

<u>Infectious diseases epidemic threats and mass gatherings: refocusing global attention on the continuing spread of the Middle East Respiratory syndrome coronavirus (MERS-CoV)</u>

Alimuddin Zumla, Abdulaziz N. Alagaili, Matthew Cotten and Esam I. Azhar

BMC Medicine 2016 14:132 Published on: 7 September 2016

Abstract

Media and World Health Organization (WHO) attention on Zika virus transmission at the 2016 Rio Olympic Games and the 2015 Ebola virus outbreak in West Africa diverted the attention of global public health authorities from other lethal infectious diseases with epidemic potential. Mass gatherings such as the annual Hajj pilgrimage hosted by Kingdom of Saudi Arabia attract huge crowds from all continents, creating high-risk conditions for the rapid global spread of infectious diseases. The highly lethal Middle Eastern respiratory syndrome coronavirus (MERS-CoV) remains in the WHO list of top emerging diseases likely to cause major epidemics. The 2015 MERS-CoV outbreak in South Korea, in which 184 MERS cases including 33 deaths occurred in 2 months, that was imported from the Middle East by a South Korean businessman was a wake-up call for the global community to refocus attention on MERS-CoV and other emerging and re-emerging infectious diseases with epidemic potential. The international donor community and Middle Eastern countries should make available resources for, and make a serious commitment to, taking forward a "One Health" global network for proactive surveillance, rapid detection, and prevention of MERS-CoV and other epidemic infectious diseases threats.

Research article

<u>Spatiotemporal dynamics of the Ebola epidemic in Guinea and implications for vaccination and disease elimination: a computational modeling analysis</u>

Marco Ajelli, Stefano Merler, Laura Fumanelli, Ana Pastore y Piontti, Natalie E. Dean, Ira M. Longini, M. Elizabeth Halloran and Alessandro Vespignani

Abstract

Background

Among the three countries most affected by the Ebola virus disease outbreak in 2014–2015, Guinea presents an unusual spatiotemporal epidemic pattern, with several waves and a long tail in the decay of the epidemic incidence.

Methods

Here, we develop a stochastic agent-based model at the level of a single household that integrates detailed data on Guinean demography, hospitals, Ebola treatment units, contact tracing, and safe burial interventions. The microsimulation-based model is used to assess the effect of each control strategy and the probability of elimination of the epidemic according to different intervention scenarios, including ring vaccination with the recombinant vesicular stomatitis virus-vectored vaccine.

Results

The numerical results indicate that the dynamics of the Ebola epidemic in Guinea can be quantitatively explained by the timeline of the implemented interventions. In particular, the early availability of Ebola treatment units and the associated isolation of cases and safe burials helped to limit the number of Ebola cases experienced by Guinea. We provide quantitative evidence of a strong negative correlation between the time series of cases and the number of traced contacts. This result is confirmed by the computational model that suggests that contact tracing effort is a key determinant in the control and elimination of the disease. In data-driven microsimulations, we find that tracing at least 5–10 contacts per case is crucial in preventing epidemic resurgence during the epidemic elimination phase. The computational model is used to provide an analysis of the ring vaccination trial highlighting its potential effect on disease elimination.

Conclusions

We identify contact tracing as one of the key determinants of the epidemic's behavior in Guinea, and we show that the early availability of Ebola treatment unit beds helped to limit the number of Ebola cases in Guinea.

BMC Pregnancy and Childbirth

http://www.biomedcentral.com/bmcpregnancychildbirth/content (Accessed 10 September 2016) [No new relevant content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles (Accessed 10 September 2016)

Research article

The social patterning of risk factors for noncommunicable diseases in five countries: evidence from the modeling the epidemiologic transition study (METS)

Associations between socioeconomic status (SES) and risk factors for noncommunicable diseases (NCD-RFs) may differ in populations at different stages of the epidemiological transition. We assessed the social p...

Silvia Stringhini, Terrence E. Forrester, Jacob Plange-Rhule, Estelle V. Lambert, Bharathi Viswanathan, Walter Riesen, Wolfgang Korte, Naomi Levitt, Liping Tong, Lara R. Dugas, David Shoham, Ramon A. Durazo-Arvizu, Amy Luke and Pascal Bovet

Debate

Schools of public health in low and middle-income countries: an imperative investment for improving the health of populations?

Public health has multicultural origins. By the close of the nineteenth century, Schools of Public Health (SPHs) began to emerge in western countries in response to major contemporary public health challenges....

Fauziah Rabbani, Leah Shipton, Franklin White, Iman Nuwayhid, Leslie London, Abdul Ghaffar, Bui Thi Thu Ha, Göran Tomson, Rajiv Rimal, Anwar Islam, Amirhossein Takian, Samuel Wong, Shehla Zaidi, Kausar Khan, Rozina Karmaliani, Imran Naeem Abbasi...

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 10 September 2016)
[No new relevant content identified]

BMJ Open

2016, Volume 6, Issue 9 http://bmjopen.bmj.com/content/current [Reviewed earlier]

Bulletin of the World Health Organization

Volume 94, Number 9, September 2016, 633-708 http://www.who.int/bulletin/volumes/94/9/en/ [Reviewed earlier]

Child Care, Health and Development

September 2016 Volume 42, Issue 5 Pages 603–773 http://onlinelibrary.wiley.com/doi/10.1111/cch.v42.5/issuetoc [Reviewed earlier]

Clinical Therapeutics

August 2016 Volume 38, Issue 8, p1773-1922 http://www.clinicaltherapeutics.com/current [New issue: No relevant content identified]

Complexity

July/August 2016 Volume 21, Issue 6 Pages 1–459 http://onlinelibrary.wiley.com/doi/10.1002/cplx.v21.6/issuetoc

[Reviewed earlier]

Conflict and Health

http://www.conflictandhealth.com/ [Accessed 10 September 2016] [No new relevant content identified]

Contemporary Clinical Trials

Volume 50, In Progress (September 2016) http://www.sciencedirect.com/science/journal/15517144/50 [New issue: No relevant content identified]

Current Opinion in Infectious Diseases

October 2016 - Volume 29 - Issue 5 pp: v-vi,433-537 http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx [New issue: No relevant content identified]

Developing World Bioethics

August 2016 Volume 16, Issue 2 Pages 61–120 http://onlinelibrary.wiley.com/doi/10.1111/dewb.2016.16.issue-2/issuetoc [Reviewed earlier]

Development in Practice

Volume 24, Number 8 http://www.developmentinpractice.org/journals/volume-24-number-8 [Reviewed earlier]

Disasters

July 2016 Volume 40, Issue 3 Pages 385–588 http://onlinelibrary.wiley.com/doi/10.1111/disa.2016.40.issue-3/issuetoc [Reviewed earlier]

Emerging Infectious Diseases

Volume 22, Number 9—September 2016 http://wwwnc.cdc.gov/eid/ [Reviewed earlier]

Epidemics

Volume 16, In Progress (September 2016) http://www.sciencedirect.com/science/journal/17554365

[Reviewed earlier]

Epidemiology and Infection

Volume 144 - Issue 12 - September 2016 http://journals.cambridge.org/action/displayIssue?jid=HYG&tab=currentissue [Reviewed earlier]

The European Journal of Public Health

Volume 26, Issue 4, 1 August 2016 http://eurpub.oxfordjournals.org/content/26/4 [Reviewed earlier]

Eurosurveillance

Volume 21, Issue 36, 08 September 2016 http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678 [No relevant content identified]

Global Health: Science and Practice (GHSP)

June 2016 | Volume 4 | Issue 2 http://www.ghspjournal.org/content/current [Reviewed earlier]

Global Public Health

Volume 11, Issue 9, 2016 http://www.tandfonline.com/toc/rgph20/current [Reviewed earlier]

Globalization and Health

http://www.globalizationandhealth.com/ [Accessed 10 September 2016] Research

<u>Mapping of research on maternal health interventions in low- and middle-income countries: a review of 2292 publications between 2000 and 2012</u>

Matthew Chersich, Duane Blaauw, Mari Dumbaugh, Loveday Penn-Kekana, Siphiwe Thwala, Leon Bijlmakers, Emily Vargas, Elinor Kern, Josephine Kavanagh, Ashar Dhana, Francisco Becerra-Posada, Langelihle Mlotshwa, Victor Becerril-Montekio, Priya Mannava, Stanley Luchters, Minh Duc Pham...

Published on: 6 September 2016

Health Affairs

September 2016; Volume 35, Issue 9

http://content.healthaffairs.org/content/current

Issue Focus: Payment Reforms, Prescription Drugs & More Global

<u>Training And Supervision Did Not Meaningfully Improve Quality Of Care For Pregnant Women</u> <u>Or Sick Children In Sub-Saharan Africa</u>

Hannah H. Leslie, Anna Gage, Humphreys Nsona, Lisa R. Hirschhorn, and Margaret E. Kruk Health Aff September 2016 35:1716-1724; doi:10.1377/hlthaff.2016.0261 Abstract

In-service training courses and supportive supervision of health workers are among the most common interventions to improve the quality of health care in low- and middle-income countries. Despite extensive investment from donors, evaluations of the long-term effect of these two interventions are scarce. We used nationally representative surveys of health systems in seven countries in sub-Saharan Africa to examine the association of in-service training and supervision with provider quality in antenatal and sick child care. The results of our analysis showed that observed quality of care was poor, with fewer than half of evidence-based actions completed by health workers, on average. In-service training and supervision were associated with quality of sick child care; they were associated with quality of antenatal care only when provided jointly. All associations were modest—at most, improvements related to interventions were equivalent to 2 additional provider actions out of the 18–40 actions expected per visit. Inservice training and supportive supervision as delivered were not sufficient to meaningfully improve the quality of care in these countries. Greater attention to the quality of health professional education and national health system performance will be required to provide the standard of health care that patients deserve.

Health and Human Rights

Volume 18, Issue 1, June 2016 http://www.hhrjournal.org/

Special Section: Tuberculosis and the Right to Health

in collaboration with the International Human Rights Clinic, University of Chicago Law School [Reviewed earlier]

Health Economics, Policy and Law

Volume 11 - Issue 03 - July 2016 http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue [Reviewed earlier]

Health Policy and Planning

Volume 31 Issue 7 September 2016 http://heapol.oxfordjournals.org/content/current [Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content [Accessed 10 September 2016] [No new relevant content identified]

Humanitarian Exchange Magazine

Number 66 April 2016
http://odihpn.org/magazine/humanitarian-innovation/
Focus: Humanitarian Innovation
by Humanitarian Practice Network and Kim Scriven April 2016
[Reviewed earlier]

Infectious Agents and Cancer

http://www.infectagentscancer.com/content [Accessed 10 September 2016] [No new content identified]

Infectious Diseases of Poverty

http://www.idpjournal.com/content [Accessed 10 September 2016] Research Article

Bibliometric study of research and development for neglected diseases in the BRICS

Large numbers of people are suffering from a group of diseases that mainly affect developing countries, as there are no available or affordable products for prevention or treatment. Research and development (R...

Jing Bai, Wei Li, Yang-Mu Huang and Yan Guo

International Health

Volume 8 Issue 4 July 2016 http://inthealth.oxfordjournals.org/content/current [Reviewed earlier]

International Journal of Epidemiology

Volume 45 Issue 3 June 2016
http://ije.oxfordjournals.org/content/current
[New issue: No relevant content identified]

International Journal of Infectious Diseases

August 2016 Volume 49, p1-210 Open Access http://www.ijidonline.com/current [Reviewed earlier]

JAMA

September 6, 2016, Vol 316, No. 9 http://jama.jamanetwork.com/issue.aspx Editorial

<u>The Challenge of Latent TB Infection</u> FREE Henry M. Blumberg, MD; Joel D. Ernst, MD

US Preventive Services Task Force Recommendation Statement

Screening for Latent Tuberculosis Infection in Adults: US Preventive Services Task Force Recommendation Statement FREE

Evidence Report

<u>Primary Care Screening and Treatment for Latent Tuberculosis Infection in Adults: Evidence Report and Systematic Review for the US Preventive Services Task Force</u> FREE Leila C. Kahwati, MD, MPH; Cynthia Feltner, MD, MPH; Michael Halpern, MD, PhD, MPH; Carol L. Woodell, BSPH; Erin Boland, BA; Halle R. Amick, MSPH; Rachel Palmieri Weber, PhD; Daniel E. Jonas, MD, MPH

JAMA Pediatrics

September 2016, Vol 170, No. 9 http://archpedi.jamanetwork.com/issue.aspx Editorial

<u>Infant Protection Against Influenza Through Maternal Immunization: A Call for More Immunogenic Vaccines</u>

Flor M. Munoz, MD

Original Investigation

<u>Duration of Infant Protection Against Influenza Illness Conferred by Maternal Immunization: Secondary Analysis of a Randomized Clinical Trial</u>

Marta C. Nunes, PhD; Clare L. Cutland, MD; Stephanie Jones, MD; Andrea Hugo, MD; Richard Madimabe, BTech; Eric A. F. Simões, MD; Adriana Weinberg, MD; Shabir A. Madhi, MD, PhD; for the Maternal Flu Trial Team

Abstract

Importance

Influenza immunization of women during pregnancy protects the young infants against influenza illness. The duration of this protection remains unclear.

Objective

To evaluate the duration of infant protection conferred by maternal immunization and its association with transplacental antibody transfer.

Design, Setting, and Participants

Infants born to women who participated in a randomized, double-blind, placebo-controlled clinical trial in 2011 and 2012 on the safety, immunogenicity, and efficacy of trivalent inactivated influenza vaccine (IIV3) during pregnancy were followed up during the first 6 months of life for polymerase chain reaction (PCR)—confirmed influenza illness. In a secondary analysis of a subset of infants, hemagglutination inhibition (HAI) antibodies were measured.

The study was performed at a single center in South Africa. The secondary analysis was performed in October 2014.

Exposure

Maternal immunization for influenza.

Main Outcomes and Measures

The vaccine's efficacy against PCR-confirmed influenza illness and the percentage of infants with HAI titers of 1:40 or more by age group.

Results

There were 1026 infants (47.2% female) born to IIV3 recipients and 1023 infants (47.3% female) born to placebo recipients who were included in the analysis of the vaccine's efficacy. The vaccine's efficacy against PCR-confirmed influenza illness was highest among infants 8 weeks of age or younger at 85.6% (95% CI, 38.3%-98.4%) and decreased with increasing age to 25.5% (95% CI, -67.9% to 67.8%) among infants 8 to 16 weeks of age and to 30.3% (95% CI, -154.9% to 82.6%) among infants 16 to 24 weeks of age. Similarly, in the IIV3 group, the percentage of infants with HAI titers of 1:40 or more to the influenza vaccine strains decreased from more than 56% in the first week of life to less than 40% at 16 weeks of age and less than 10.0% at 24 weeks of age.

Conclusions and Relevance

Maternal immunization conferred protection against infection in the infants for a limited period during early life. The lack of protection beyond 8 weeks of age correlated with a decrease in maternally derived antibodies.

Trial Registration

clinicaltrials.gov Identifier: NCT01306669

Journal of Community Health

Volume 41, Issue 5, October 2016 http://link.springer.com/journal/10900/41/5/page/1

[New issue: No relevant content identified]

Journal of Epidemiology & Community Health

October 2016, Volume 70, Issue 10 http://jech.bmj.com/content/current

Theory and methods

Harmonising summary measures of population health using global survey instruments Nicolas Berger, Jean-Marie Robine, Toshiyuki Ojima, Jennifer Madans, Herman Van Oyen J Epidemiol Community Health 2016;70:1039-1044 Published Online First: 10 May 2016 doi:10.1136/jech-2015-206870

Journal of Global Ethics

Volume 12, Issue 2, 2016 http://www.tandfonline.com/toc/rjge20/current [Reviewed earlier]

Journal of Global Infectious Diseases (JGID)

July-September 2016 Volume 8 | Issue 3 Page Nos. 95-126 http://www.jgid.org/currentissue.asp?sabs=n [Reviewed earlier]

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

Volume 27, Number 3, August 2016 https://muse.jhu.edu/issue/33980 [Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 18, Issue 5, October 2016 http://link.springer.com/journal/10903/18/5/page/1 Original Paper

<u>Latent Tuberculosis Infection Among Immigrant and Refugee Children Arriving in the United</u> States: 2010

Eboni M. Taylor, John Painter, Drew L. Posey...

Original Paper

Behavioral and Environmental Explanations of Elevated Blood Lead Levels in Immigrant Children and Children of Immigrants

Stan A. Kaplowitz, <u>Harry Perlstadt</u>...

Original Paper

Immunization Coverage in Migrant School Children Along the Thailand-Myanmar Border Aiko Kaji, Daniel M. Parker, Cindy S. Chu...

Original Paper

HPV Vaccine and Latino Immigrant Parents: If They Offer It, We Will Get It Abraham Aragones, Margaux Genoff...

Journal of Immigrant & Refugee Studies

Volume 14, Issue 3, 2016

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

Special Issue: Social Mobilization and Political Participation in the Diaspora During the "Arab Spring"

[Reviewed earlier]

Journal of Infectious Diseases

Volume 214 Issue 6 September 15, 2016 http://jid.oxfordjournals.org/content/current EDITORIAL COMMENTARIES

Editor's choice: Dengue Vaccine: The Need, the Challenges, and Progress

Alan L. Rothman and Francis A. Ennis

J Infect Dis. (2016) 214 (6): 825-827 doi:10.1093/infdis/jiw068

<u>Public Health Benefits of Routine Human Papillomavirus Vaccination for Adults in the</u> Netherlands: A Mathematical Modeling Study

Suzette M. Matthijsse, Jan A. C. Hontelez, Steffie K. Naber, Kirsten Rozemeijer, Inge M. C. M. de Kok, Roel Bakker, Marjolein van Ballegooijen, Joost van Rosmalen, and Sake J. de Vlas J Infect Dis. (2016) 214 (6): 854-861 doi:10.1093/infdis/jiw256

The Journal of Law, Medicine & Ethics

Winter 2015 Volume 43, Issue 4 Pages 673–913 http://onlinelibrary.wiley.com/doi/10.1111/jlme.2015.43.issue-4/issuetoc

Special Issue: SYMPOSIUM: Harmonizing Privacy Laws to Enable International Biobank Research: Part I

[14 articles]
[Reviewed earlier]

Journal of Medical Ethics

September 2016, Volume 42, Issue 9 http://jme.bmj.com/content/current [Reviewed earlier]

Journal of Medical Internet Research

Vol 18, No 7 (2016): July http://www.jmir.org/2016/7 [Reviewed earlier]

Journal of Medical Microbiology

Volume 65, Issue 8, August 2016

http://jmm.microbiologyresearch.org/content/journal/jmm/65/8;jsessionid=8n8h02en4abqh.x-sqm-live-02

[New issue; No relevant digest content identified]

Journal of Patient-Centered Research and Reviews

Volume 3, Issue 3 (2016) http://digitalrepository.aurorahealthcare.org/jpcrr/ [Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)

Volume 5 Issue 10 September 2016 http://jpids.oxfordjournals.org/content/current [Reviewed earlier]

Journal of Pediatrics

September 2016 Volume 176, p1-228 http://www.jpeds.com/current [New issue; No relevant digest content identified]

Journal of Public Health Policy

Volume 37, Issue 3, August 2016 http://link.springer.com/journal/41271/37/3/page/1 [Reviewed earlier

Journal of the Royal Society - Interface

01 June 2016; volume 13, issue 119 http://rsif.royalsocietypublishing.org/content/current [Reviewed earlier]

Journal of Virology

September 2016, volume 90, issue 18 http://jvi.asm.org/content/current [New issue; No relevant digest content identified]

The Lancet

Sep 10, 2016 Volume 388 Number 10049 p1025-1128 e2-e3 http://www.thelancet.com/journals/lancet/issue/current Series

HIV and related infections in prisoners

Global burden of HIV, viral hepatitis, and tuberculosis in prisoners and detainees
Kate Dolan, Andrea L Wirtz, Babak Moazen, Martial Ndeffo-mbah, Alison Galvani, Stuart A
Kinner, Ryan Courtney, Martin McKee, Joseph J Amon, Lisa Maher, Margaret Hellard, Chris
Beyrer, Fredrick L Altice

HIV and related infections in prisoners

Clinical care of incarcerated people with HIV, viral hepatitis, or tuberculosis

Josiah D Rich, Curt G Beckwith, Alexandria Macmadu, Brandon D L Marshall, Lauren Brinkley-Rubinstein, Joseph J Amon, M-J Milloy, Maximilian R F King, Jorge Sanchez, Lukoye Atwoli, Frederick L Altice

HIV and related infections in prisoners

<u>Prevention of transmission of HIV, hepatitis B virus, hepatitis C virus, and tuberculosis in prisoners</u>

Adeeba Kamarulzaman, Stewart E Reid, Amee Schwitters, Lucas Wiessing, Nabila El-Bassel, Kate Dolan, Babak Moazen, Andrea L Wirtz, Annette Verster, Frederick L Altice 1115

Lancet Global Health

Sep 2016 Volume 4 Number 9 e579-e662 http://www.thelancet.com/journals/langlo/issue/current [Reviewed earlier]

The Lancet Infectious Diseases

Sep 2016 Volume 16 Number 9 p981-1084 e178-e201 http://www.thelancet.com/journals/laninf/issue/current [Reviewed earlier]

Maternal and Child Health Journal

Volume 20, Issue 9, September 2016 http://link.springer.com/journal/10995/20/9/page/1 [Reviewed earlier]

Medical Decision Making (MDM)

August 2016; 36 (6) http://mdm.sagepub.com/content/current [Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy
June 2016 Volume 94, Issue 2 Pages 225–435
http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.2016.94.issue-2/issuetoc
[Reviewed earlier]

Nature

Volume 537 Number 7619 pp137-1906 8 September 2016 http://www.nature.com/nature/current issue.html
[New issue; No relevant digest content identified]

Nature Medicine

September 2016, Volume 22 No 9 pp963-1061 http://www.nature.com/nm/journal/v22/n9/index.html [New issue; No relevant digest content identified]

Nature Reviews Immunology

September 2016 Vol 16 No 9 http://www.nature.com/nri/journal/v16/n9/index.html [Reviewed earlier]

New England Journal of Medicine

September 8, 2016 Vol. 375 No. 10 http://www.nejm.org/toc/nejm/medical-journal Perspective New Lyme Disease Vaccine

S.A. Plotkin

Despite the development of two vaccines against *Borrelia burgdorferi*, the bacterium that causes Lyme disease, there is no such vaccine currently on the market. But the problem of Lyme disease is large and growing. Fortunately, the future seems reasonably bright for new vaccines.

Review Article

<u>The Changing Face of Clinical Trials: The Primary Outcome Is Positive — Is That Good Enough?</u>
S.J. Pocock and G.W. Stone

There is a natural tendency to simplify the findings of a clinical trial into a binary conclusion: "Was there a positive outcome — or not?" In order to address this question with some objectivity, attention is typically focused on whether the prespecified measure of success for the primary outcome has been met — that is, whether a P value of less than 0.05 has been achieved for the difference in treatments. In reality, a more nuanced interpretation requires a thorough examination of the totality of the evidence, including secondary end points, safety issues, and the size and quality of the trial. In this article, which focuses on the evaluation of "positive" studies — as in our previous article, 1 which focused on the appraisal of "negative" studies — our intent is to facilitate a more sophisticated and balanced interpretation of trial evidence. Again, we make our points using examples from trials involving cardiovascular disease (our area of expertise), but the messages can be easily applied to other subject areas.

Pediatrics

September 2016, VOLUME 138 / ISSUE 3 http://pediatrics.aappublications.org/content/138/2?current-issue=y [Reviewed earlier]

Pharmaceutics

Volume 8, Issue 2 (June 2016) http://www.mdpi.com/1999-4923/8/2 [Reviewed earlier]

PharmacoEconomics

Volume 34, Issue 9, September 2016 http://link.springer.com/journal/40273/34/9/page/1 [Reviewed earlier]

PLOS Currents: Disasters

http://currents.plos.org/disasters/ [Accessed 10 September 2016] [No new content identified]

PLoS Currents: Outbreaks

http://currents.plos.org/outbreaks/ (Accessed 10 September 2016)

<u>Isolation of Zika Virus Imported from Tonga into Australia</u>

September 7, 2016 · Research Article

Introduction: The globally emergent Zika virus (ZIKV) is a threat to Australia, given the number of imported cases from epidemic regions and the presence of competent mosquito vectors. We report the isolation of ZIKV from a female traveler who recently returned from Tonga to Brisbane, Queensland, Australia in 2016.

Methods: A specific TaqMan real-time reverse transcriptase polymerase chain reaction assay (RT-PCR) assay was used to detect ZIKV in serum and urine samples. Conventional cell culture techniques and suckling mice were employed in an attempt to isolate ZIKV from serum and urine.

Results: A ZIKV isolate (TS17-2016) was recovered from the serum sample after one passage in suckling mouse brains and harvested 11 days post inoculation. Phylogenetic analysis of complete envelope (E) gene sequences demonstrated TS17-2016 shared 99.9% nucleotide identity with other contemporary sequences from Tonga 2016, Brazil 2015 and French Polynesia 2013 within the Asian lineage.

Discussion: This is the first known report of successful isolation of ZIKV from a human clinical sample in Australia and the first from a traveler from Tonga. This study highlights the potential difficulties in isolating ZIKV from acute clinical samples using conventional cell culture techniques, particularly in non-endemic countries like Australia where access to samples of sufficient viral load is limited. The successful isolation of TS17-2016 will be essential for continued investigations of ZIKV transmission and pathogenicity and will enable the advancement of new preventative control measures extremely relevant to the Australian and Pacific region.

PLoS Medicine

http://www.plosmedicine.org/ (Accessed 10 September 2016) Research Article

<u>Sex Differences in Tuberculosis Burden and Notifications in Low- and Middle-Income Countries:</u>
A Systematic Review and Meta-analysis

Katherine C. Horton, Peter MacPherson, Rein M. G. J. Houben, Richard G. White, Elizabeth L. Corbett

| published 06 Sep 2016 PLOS Medicine http://dx.doi.org/10.1371/journal.pmed.1002119

A Médecins Sans Frontières Ethics Framework for Humanitarian Innovation

Julian Sheather, Kiran Jobanputra, Doris Schopper, John Pringle, Sarah Venis, Sidney Wong, Robin Vincent-Smith

Health in Action | published 06 Sep 2016 PLOS Medicine

PLoS Neglected Tropical Diseases

http://www.plosntds.org/

[Accessed 10 September 2016]

Research Article

The Global Economic and Health Burden of Human Hookworm Infection

Sarah M. Bartsch, Peter J. Hotez, Lindsey Asti, Kristina M. Zapf, Maria Elena Bottazzi, David J.

Diemert, Bruce Y. Lee

published 08 Sep 2016 PLOS Neglected Tropical Diseases

http://dx.doi.org/10.1371/journal.pntd.0004922

PLoS One

http://www.plosone.org/

[Accessed 10 September 2016]

Research Article

<u>Pre-Vaccination Care-Seeking in Females Reporting Severe Adverse Reactions to HPV Vaccine. A</u> Registry Based Case-Control Study

Kåre Mølbak, Niels Dalum Hansen, Palle Valentiner-Branth

| published 09 Sep 2016 PLOS ONE

http://dx.doi.org/10.1371/journal.pone.0162520

Research Article

Experimental Treatment of Ebola Virus Disease with Brincidofovir

Jake Dunning, Stephen B. Kennedy, Annick Antierens, John Whitehead, Iza Ciglenecki, Gail Carson, Rupa Kanapathipillai, Lyndsey Castle, Rebecca Howell-Jones, Raul Pardinaz-Solis, Jennifer Grove, Janet Scott, Trudie Lang, Piero Olliaro, Peter W. Horby, for the RAPIDE-BCV trial team

| published 09 Sep 2016 PLOS ONE

http://dx.doi.org/10.1371/journal.pone.0162199

PLoS Pathogens

http://journals.plos.org/plospathogens/ (Accessed 10 September 2016)

[No new relevant content identified]

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

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

(Accessed 10 September 2016)

Sufficient trial size to inform clinical practice

Charles F. Manskia, 1 and Aleksey Tetenovb,c

Author Affiliations

Contributed by Charles F. Manski, July 23, 2016 (sent for review May 20, 2016; reviewed by Keisuke Hirano and David Meltzer)

Significance

A core objective of trials comparing alternative medical treatments is to inform treatment choice in clinical practice, and yet conventional practice in designing trials has been to choose a sample size that yields specified statistical power. Power, a concept in the theory of hypothesis testing, is at most loosely connected to effective treatment choice. This paper develops an alternative principle for trial design that aims to directly benefit medical decision making. We propose choosing a sample size that enables implementation of near-optimal treatment rules. Near optimality means that treatment choices are suitably close to the best that could be achieved if clinicians were to know with certainty mean treatment response in their patient populations.

Abstract

Medical research has evolved conventions for choosing sample size in randomized clinical trials that rest on the theory of hypothesis testing. Bayesian statisticians have argued that trials should be designed to maximize subjective expected utility in settings of clinical interest. This perspective is compelling given a credible prior distribution on treatment response, but there is rarely consensus on what the subjective prior beliefs should be. We use Wald's frequentist statistical decision theory to study design of trials under ambiguity. We show that ϵ -optimal rules exist when trials have large enough sample size. An ϵ -optimal rule has expected welfare within ϵ of the welfare of the best treatment in every state of nature. Equivalently, it has maximum regret no larger than ϵ . We consider trials that draw predetermined numbers of subjects at random within groups stratified by covariates and treatments. We report exact results for the special case of two treatments and binary outcomes. We give simple sufficient conditions on sample sizes that ensure existence of ϵ -optimal treatment rules when there are multiple treatments and outcomes are bounded. These conditions are obtained by application of Hoeffding large deviations inequalities to evaluate the performance of empirical success rules.

Prehospital & Disaster Medicine

Volume 31 - Issue 04 - August 2016 https://journals.cambridge.org/action/displayIssue?jid=PDM&tab=currentissue [Reviewed earlier]

Preventive Medicine

Volume 89, Pages 1-348 (August 2016) http://www.sciencedirect.com/science/journal/00917435/89 [Reviewed earlier]

Proceedings of the Royal Society B

10 February 2016; volume 283, issue 1824 http://rspb.royalsocietypublishing.org/content/283/1824?current-issue=y [Reviewed earlier]

Public Health Ethics

Volume 9 Issue 10 September 2016 http://phe.oxfordjournals.org/content/current [Reviewed earlier]

Public Health Reports

Volume 131 Issue Number 4 July/August 2016 http://phr.sagepub.com/content/current [Reviewed earlier]

Qualitative Health Research

September 2016; 26 (11) http://ghr.sagepub.com/content/current

Special Issue: HIV & Sexual Health [13 artticles]

[Reviewed earlier]

Reproductive Health

http://www.reproductive-health-journal.com/content [Accessed 10 September 2016] [No new relevant content identified]

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

Recently Published Articles - July http://www.paho.org/journal/index.php?option=com content&view=featured&Itemid=101 [Reviewed earlier]

Risk Analysis

August 2016 Volume 36, Issue 8 Pages 1511–1681 http://onlinelibrary.wiley.com/doi/10.1111/risa.2016.36.issue-8/issuetoc [Reviewed earlier]

Risk Management and Healthcare Policy

Volume 9, 2016 https://www.dovepress.com/risk-management-and-healthcare-policy-archive56 [Accessed 10 September 2016] No new content identified]

Science

09 September 2016 Vol 353, Issue 6304 http://www.sciencemag.org/current.dtl Editorial

Ebola and Zika: Cautionary tales

By Michael T. Osterholm Science09 Sep 2016: 1073

Summary

The emergence of Zika in the Americas is a stark reminder of how quickly public health challenges of infectious diseases can change. The need for a safe and effective vaccine is immediate. Yet, like the Ebola epidemic 2 years ago, we find ourselves without a vaccine to combat this latest threat. When surveillance points to a possible emergence of a new infectious disease of potential public health importance, we need procedural and funding mechanisms that can quickly identify candidate vaccines and drive research and development toward licensure and production. Even if such a vaccine is not yet licensed, having it ready for immediate large trials when a regional crisis occurs will be a major advantage over our current reactive system.

Editorial

Zika vaccine trials

By Marc Lipsitch, Benjamin J. Cowling

Science09 Sep 2016: 1094-1095 Full Access

There are new and familiar challenges in the race for timely and effective vaccines Summary

Promising data for candidate vaccines against Zika virus infection reported by Abbink et al. (1) on page 1129 of this issue raise hopes that one or more Zika virus vaccines may soon be ready for efficacy trials. Recent years have seen a barrage of emerging infectious diseases, including those caused by new pathogens such as Middle East respiratory syndrome (MERS) coronavirus, and those that are newly salient because of increased geographic spread, higher incidence, or genetic change, such as influenza A(H1N1)pdm09, Ebola virus, and Zika virus. Developing effective vaccines is a central goal for such pathogens.

Research Articles

Protective efficacy of multiple vaccine platforms against Zika virus challenge in rhesus monkeys By Peter Abbink, Rafael A. Larocca, Rafael A. De La Barrera, Christine A. Bricault, Edward T. Moseley, Michael Boyd, Marinela Kirilova, Zhenfeng Li, David Ng'ang'a, Ovini Nanayakkara, Ramya Nityanandam, Noe B. Mercado, Erica N. Borducchi, Arshi Agarwal, Amanda L. Brinkman, Crystal Cabral, Abishek Chandrashekar, Patricia B. Giglio, David Jetton, Jessica Jimenez, Benjamin C. Lee, Shanell Mojta, Katherine Molloy, Mayuri Shetty, George H. Neubauer, Kathryn E. Stephenson, Jean Pierre S. Peron, Paolo M. de A. Zanotto, Johnathan Misamore, Brad Finneyfrock, Mark G. Lewis, Galit Alter, Kayvon Modjarrad, Richard G. Jarman, Kenneth H. Eckels, Nelson L. Michael, Stephen J. Thomas, Dan H. Barouch

Science09 Sep 2016: 1129-1132

Abstract

Zika virus (ZIKV) is responsible for a major ongoing epidemic in the Americas and has been causally associated with fetal microcephaly. The development of a safe and effective ZIKV vaccine is therefore an urgent global health priority. Here we demonstrate that three different vaccine platforms protect against ZIKV challenge in rhesus monkeys. A purified inactivated virus vaccine induced ZIKV-specific neutralizing antibodies and completely protected monkeys against ZIKV strains from both Brazil and Puerto Rico. Purified immunoglobulin from vaccinated monkeys also conferred passive protection in adoptive transfer studies. A plasmid DNA vaccine and a single-shot recombinant rhesus adenovirus serotype 52 vector vaccine, both expressing ZIKV premembrane and envelope, also elicited neutralizing antibodies and completely protected

monkeys against ZIKV challenge. These data support the rapid clinical development of ZIKV vaccines for humans.

Science Translational Medicine

07 September 2016 Vol 8, Issue 355 http://stm.sciencemag.org/

[New issue: No relevant content identified]

Social Science & Medicine

Volume 160, Pages 1-130 (July 2016) http://www.sciencedirect.com/science/journal/02779536/160 [Reviewed earlier]

Tropical Medicine & International Health

September 2016 Volume 21, Issue 9 Pages 1059–1196 http://onlinelibrary.wiley.com/doi/10.1111/tmi.2016.21.issue-9/issuetoc [Reviewed earlier]

Vaccine

Volume 34, Issue 39, Pages 4643-4762 (7 September 2016) http://www.sciencedirect.com/science/journal/0264410X/34/39 Reviews

<u>Vaccine-preventable disease and the under-utilization of immunizations in complex</u> humanitarian emergencies

Review Article Pages 4649-4655

Ryan M. Close, Catherine Pearson, Jennifer Cohn

Abstract

Complex humanitarian emergencies affect 40–60 million people annually and are a growing public health concern worldwide. Despite efforts to provide medical and public health services to populations affected by complex emergencies, significant morbidity and mortality persist. Measles is a major communicable disease threat, but through vaccination of broader target age groups beyond the traditional immunization schedule, measles-related mortality has been significantly reduced during crises. Yet, a limited number of vaccine-preventable diseases continue to contribute disproportionately to morbidity and mortality in complex emergencies. The literature suggests that Streptococcus pneumoniae, Rotavirus, and Haemophilus influenzae type-b should be key targets for vaccination programs. Because of the significant contribution of these three pathogens to complex humanitarian emergencies in low and middle-income countries regardless of disaster type, geography, or population, their vaccines should be considered essential components of the standard emergency response effort. We discuss the barriers to vaccine distribution and provide evidence for strategies to improve distribution, including expanded target age-range and reduced dose schedules. Our review includes specific recommendations for the expanded use of these three vaccines in complex emergencies in low and middle-income countries as a way to guide future policy discussions.

Original Research Article

Uptake and timeliness of rotavirus vaccination in Norway: The first year post-introduction

Pages 4684-4689

Beatriz Valcarcel Salamanca, Maria Elisabeth Hagerup-Jenssen, Elmira Flem Abstract

Background

To minimise vaccine-associated risk of intussusception following rotavirus vaccination, Norway adopted very strict age limits for initiating and completing the vaccine series at the time rotavirus vaccination was included in the national immunisation programme, October 2014. Although Norway has a high coverage for routine childhood vaccines, these stringent age limits could negatively affect rotavirus coverage. We documented the status and impact of rotavirus vaccination on other infant vaccines during the first year after its introduction. Methods

We used individual vaccination data from the national immunisation register to calculate coverage for rotavirus and other vaccines and examine adherence with the recommended schedules. We identified factors associated with completing the full rotavirus series by performing multiple logistic regression analyses. We also evaluated potential changes in uptake and timeliness of other routine vaccines after the introduction of rotavirus vaccine using the Kaplan-Meier method.

Results

The national coverage for rotavirus vaccine achieved a year after the introduction was 89% for one dose and 82% for two doses, respectively. Among fully rotavirus-vaccinated children, 98% received both doses within the upper age limit and 90% received both doses according to the recommended schedule. The child's age at the initiation of rotavirus series and being vaccinated with diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b (DTaP/IPV/Hib) and pneumococcal vaccines were the strongest predictors of completing the full rotavirus series. No major changes in uptake and timeliness of other paediatric vaccines were observed after introduction of rotavirus vaccine.

Conclusions

Norway achieved a high national coverage and excellent adherence with the strict age limits for rotavirus vaccine administration during the first year of introduction, indicating robustness of the national immunisation programme. Rotavirus vaccination did not impact coverage or timeliness of other infant vaccines.

Trends in childhood vaccine purchase costs in the US public sector: 1996–2014

Original Research Article

Pages 4706-4711

Weiwei Chen, Mark Messonnier, Fangjun Zhou

Abstract

While vaccination remains as one of the most cost-effective preventive strategies, the cost of fully immunizing a child has grown considerably over the last few decades. This study examines trends in non-influenza childhood vaccine purchase costs in the public sector from 1996 to 2014. Non-influenza vaccine purchase cost per child for children aged 0 through 18 years was calculated based on public-sector purchase prices. Purchase cost changes were then decomposed into changes attributable to recommendation updates and changes attributable to price variation. The study analyzed the growth rate of combination vaccine prices separately and compared these prices with the sum of prices of component vaccines. It is found that the

average annual growth rate of non-influenza vaccine purchase cost per child during 1996–2014 was 12.6%. The growth rate attributable to price changes was 1.0% on average. Combination vaccine prices showed greater variation. The study concludes that vaccine price variation was one but a minor reason for purchase cost changes. Recommendation updates, particularly the introduction of new vaccines, played a much larger role in raising the purchase costs. If the 12.6% annual growth rate found during 1996–2014 in the study continues to apply, the purchase costs of childhood vaccines may more than double by 2020.

A population based study comparing changes in rotavirus burden on the Island of Ireland between a highly vaccinated population and an unvaccinated population

Original Research Article

Pages 4718-4723

Gillian Armstrong, Naomh Gallagher, Paul Cabrey, Adele M. Graham, Paul J. McKeown, Sarah Jackson, Mary Dallat, Richard D. Smithson

Abstract

Background

Rotavirus infection is a leading cause of gastroenteritis in infants and children globally. Reductions in rotavirus activity have been observed following introduction of rotavirus vaccination programmes, however a reductions have also been reported in some unvaccinated countries.

The Island of Ireland incorporates the two jurisdictions Northern Ireland (NI) and the Republic of Ireland (IE). Both have similarities in climate, demography, morbidity and mortality but distinct health administrations and vaccination policies. Rotarix was added to the childhood immunisation programme in NI on the 1 July 2013. IE have not introduced routine rotavirus vaccination to date.

The aim of this population based ecological study was to evaluate the impact of the rotavirus vaccine on burden of rotavirus disease in NI, and to compare with IE as an unvaccinated control population. This will help determine if the changes seen were due to the rotavirus vaccine, or due to confounding factors.

Methods

A number of population based measures of disease burden were compared in both jurisdictions pre-vaccine (six years; 2007/08–2012/13) and post-vaccine (two years; 2013/14–2014/15). The data sources included national rotavirus surveillance data based on laboratory reports/notifications; hospital admission data; and notifications of gastroenteritis in under 2 year olds.

Results

In the post-vaccination period, rotavirus incidence in NI dropped by 54% while in IE it increased by 19% compared to the pre-vaccine period. Notifications of gastroenteritis in under 2 s in NI declined by 53% and hospital admissions in under 5 year olds in NI declined by 40% in the post vaccine period.

Conclusions

This natural experiment demonstrated a significant reduction in rotavirus disease activity post-vaccine introduction in NI with associated reductions in healthcare utilisation, with a concurrent increase in rotavirus disease activity in the non-vaccinated population in IE. These findings support rotavirus vaccination as an effective measure to reduce childhood morbidity.

<u>Impact of pneumococcal conjugate vaccine in children morbidity and mortality in Peru: Time</u> series analyses

Original Research Article

Pages 4738-4743

Victor Suarez, Fabiana Michel, Cristiana M. Toscano, Ana Luiza Bierrenbach, Marco Gonzales, Airlane Pereira Alencar, Cuauhtemoc Ruiz Matus, Jon K. Andrus, Lucia H. de Oliveira *Abstract*

Streptococcus pneumoniae is the leading cause of bacterial pneumonia, meningitis and sepsis in children worldwide. Despite available evidence on pneumococcal conjugate vaccine (PCV) impact on pneumonia hospitalizations in children, studies demonstrating PCV impact in morbidity and mortality in middle-income countries are still scarce. Given the disease burden, PCV7 was introduced in Peru in 2009, and then switched to PCV10 in late 2011. National public healthcare system provides care for 60% of the population, and national hospitalization, outpatient and mortality data are available.

We thus aimed to assess the effects of routine PCV vaccination on pneumonia hospitalization and mortality, and acute otitis media (AOM) and all cause pneumonia outpatient visits in children under one year of age in Peru.

We conducted a segmented time-series analysis using outcome-specific regression models. Study period was from January 2006 to December 2012. Data sources included the National information systems for hospitalization, mortality, outpatient visits, and RENACE, the national database of aggregated weekly notifications of pneumonia and other acute respiratory diseases (both hospitalized and non-hospitalized). Study outcomes included community acquired pneumonia outpatient visits, hospitalizations and deaths (ICD10 codes J12-J18); and AOM outpatient visits (H65-H67). Monthly age- and sex-specific admission, outpatient visit, and mortality rates per 100,000 children aged <1 year, as well as weekly rates for pneumonia and AOM recorded in RENACE were estimated.

After PCV introduction, we observed significant vaccine impact in morbidity and mortality in children aged <1 year. Vaccine effectiveness was 26.2% (95% CI 16.9–34.4) for AOM visits, 35% (95% CI 8.6–53.8) for mortality due to pneumonia, and 20.6% (95% CI 10.6–29.5) for weekly cases of pneumonia hospitalization and outpatient visits notified to RENACE. We used secondary data sources which are usually developed for other non-epidemiologic purposes. Despite some data limitations, our results clearly demonstrate the overall benefit of PCV vaccination in Peru.

Assessing determinants of the intention to accept a pertussis cocooning vaccination: A survey among Dutch parents

Original Research Article

Pages 4744-4751

Olga Visser, Janneke Kraan, Reinier Akkermans, Robert A.C. Ruiter, Koos van der Velden, Jeannine L.A. Hautvast, Marlies E.J.L. Hulscher

Abstract

Introduction

Pertussis cocooning is one of the strategies aiming to prevent the potential harm of pertussis in infants by vaccinating (among others) their parents. Several countries adopted this strategy, but uptake is a problem. Determinants of parental uptake are important in the design of an effective vaccination programme. Therefore, this study aims to assess parents' intention to accept a pertussis cocooning vaccination and its determinants.

Methods

A 98 item questionnaire was developed based on a theoretical framework, assessing parents' intention to accept a pertussis cocooning vaccination and its personal and psychosocial

determinants. In addition, beliefs underlying parents' attitude towards pertussis cocooning vaccination were assessed. Both logistic and linear regression analysis were used to assess univariate and multivariate associations amongst study variables.

Parents returned 282 questionnaires. The majority of the parents (78%) reported a positive intention to accept a pertussis cocooning vaccination. Attitude (OR 6.6, p < .001), anticipated negative affect in response to non acceptance (OR 1.65, p < .001), anticipated negative affect in response to acceptance (OR 0.55, p .040) and decisional uncertainty (OR 0.52, p .002) were significantly associated with intention. General vaccination beliefs (β 0.58, p < .001), moral norm (β 0.22, p < .001), perceived susceptibility of pertussis in children (β 0.10, p.004), and efficacy outcome expectations (β 0.15, p.011) were significant correlates of attitude towards pertussis cocooning vaccination.

Conclusion

The parental intention to accept a pertussis cocooning vaccination in this study is rather high. Targeting the identified determinants of parents' acceptance in a pertussis cocooning vaccination programme is crucial to secure that intention is translated into actual vaccination uptake.

Vaccine: Development and Therapy

https://www.dovepress.com/vaccine-development-and-therapy-archive111 (Accessed 10 September 2016)
[No new content]

Vaccines — Open Access Journal

http://www.mdpi.com/journal/vaccines (Accessed 10 September 2016) [No new relevant content]

Value in Health

July 2016–August 2016 Volume 19, Issue 5, p511-698 http://www.valueinhealthjournal.com/current [Reviewed earlier]

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

No new content identified.

* * * * *

Media/Policy Watch

This section is intended to alert readers to substantive news, analysis and opinion from the general media 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 10 September 2016 [No new, unique, relevant content]

BBC

http://www.bbc.co.uk/
Accessed 10 September 2016
Vaccine cooler could save millions of lives
Published Date
8 Sep 2016

...A vaccine cooler designed by a 22-year-old engineering student has won the James Dyson Award UK 2016. William Broadway tells the Today programme how the cooler, which the The World Health Organisation says could save 1.5 million lives per year, works.

The Economist

http://www.economist.com/ Accessed 10 September 2016 [No new, unique, relevant content]

Financial Times

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

Accessed 10 September 2016

[No new, unique, relevant content]

Forbes

http://www.forbes.com/ Accessed 10 September 2016

It's Past Time For Lyme Disease Vaccine, Says Vaccine Developer Stanley Plotkin

Tara Haelle, Contributor

With more than 300,000 new infections of Lyme disease each year, a vaccine is warranted, argues researcher.

Are Vaccines Getting To Where They Need to Go?

31 August 2016

Here's a news flash. While vaccines can save millions of lives and prevent much suffering, vaccines have to actually reach people to work. In other words, if a vaccine never reaches a person, it cannot protect anyone from disease. And when the vaccine is not used, it goes to waste. You may think, isn't this obvious? Sort of like, if a doughnut does not make it to your mouth, you cannot eat it? Well, for many years, vaccine supply chains seemed like Jan Brady, Robin, Silent Bob or Chewbacca of the vaccine world, getting much less attention than other seemingly "more sexy" aspects of the vaccine world such as developing new vaccines and finding ways to pay for vaccines. (Yes, I said it, Chewbacca is not as sexy as Princess Leia...or Han Solo, depending on whom you prefer.) But "less sexy" doesn't mean less important.

Foreign Affairs

http://www.foreignaffairs.com/ Accessed 10 September 2016 [No new, unique, relevant content]

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