

Vaccines and Global Health: The Week in Review 10 January 2015 Center for Vaccine Ethics & Policy (CVEP)

This weekly summary 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 6,500 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 (EDT in the U.S.). If you would like to receive the email version, please send your request to david.r.curry@centerforvaccineethicsandpolicy.org.

POLIO [to 10 January 2015] *Public Health Emergency of International Concern (PHEIC)*

GPEI Update: Polio this week - As of 7 January 2014

Global Polio Eradication Initiative [Editor's Excerpt and text bolding]

Full report: http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx

:: The last few years have seen the Global Polio Eradication Initiative (GPEI) evolve and grow in response to the threats posed to the world by the final strongholds of the poliovirus. Despite being more geographically limited than ever before, at the end of $\underline{2014}$ the virus continues to pose challenges that must be faced in 2015 if we are to protect children from this disease forever. Polio eradication efforts in 2015 will have five priorities: refining surveillance to catch

any remaining virus, keeping Africa and the Middle East polio-free, providing a surge of support to Pakistan and Afghanistan, preparing for the withdrawal of oral polio vaccine type 2 and continuing to demonstrate and build on the differences that the polio programme makes to strengthen routine immunization programmes. More

Selected country report content:

Afghanistan

- :: Two new wild poliovirus type 1 (WPV1) cases were reported in the past two weeks in Panjwayi district of Kandahar province. The most recent case had onset of paralysis on 4 December. The total number of WPV1 cases for 2014 in Afghanistan is now 28 compared to 14 in 2013. The bulk of these cases are linked to cross-border transmission with neighbouring Pakistan.
- :: Subnational Immunization Days (SNIDs) are planned for 11 13 and 25 27 January in high risk areas of the south and east using bivalent oral polio vaccine (OPV). On 15 17 February, SNIDs will take place across the entire south of the country, also using bivalent OPV. The next National Immunization Days (NIDs) are planned for March using a combination of inactivated polio vaccine (IPV) and trivalent OPV.

Nigeria

:: One new type 2 circulating vaccine-derived poliovirus (cVDPV2) case was reported in the last week. This most recent case had onset of paralysis on 16 November in Barde district of Yobe state. The total number of cVDPV2 cases for 2014 in Nigeria is now 29.

Pakistan

- :: Six new wild poliovirus type 1 (WPV1) cases were reported in the past 2 weeks. Two are from Balochistan (1 in Killa Abdullah district and the other in newly infected Chaghai district); 2 from Khyber Pakhtunkhwa (KP) province, both in Peshawar; and 2 from the Federally Administered Tribal Areas (FATA) in Khyber Agency. The total number of WPV1 cases in Pakistan in 2014 is now 297, compared to 93 in 2013. The most recent WPV1 cases had onset of paralysis on 15 December in Khyber Agency.
- :: Immunization activities are continuing with particular focus on known high-risk areas, in previously inaccessible areas of FATA. At exit and entry points of conflict-affected areas 100 permanent vaccination points are being used to reach internally displaced families as they move in and out of the inaccessible area.

West Africa

- :: The Ebola crisis in western Africa continues to have an impact on the implementation or polio eradication activities in Liberia, Guinea and Sierra Leone. Supplementary immunization activities (SIAs) in these countries have been postponed and the quality of acute flaccid paralysis surveillance has markedly decreased this year. National Immunization Days (NIDs) have been rescheduled for Guinea, Liberia and Sierra Leone from the 27 February to 31 March. The programme continues to monitor the situation with concern.
- :: Even as polio programme staff across West Africa support efforts to control the Ebola outbreak affecting the region, efforts are being made in those countries not affected by Ebola to vaccinate children against polio to create a buffer zone surrounding the Ebola-affected countries.
- :: NIDs are planned using bivalent oral polio vaccine (OPV) in Niger and Benin on 27 February to 2 March, and tentatively in Mali in March with dates to be confirmed. From the 27 to 31 March, NIDs will take place in Benin, Burkina Faso, Cote d'Ivoire, Mali, Niger and Senegal using trivalent OPV.

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EBOLA/EVD [to 10 January 2015]

Public Health Emergency of International Concern (PHEIC); "Threat to international peace and security" (UN Security Council)

Editor's Note:

Our extensive coverage of Ebola/EVD activity continues – including detailed coverage of UNMEER now available at the end of this digest and other INGO/agency activity reported in the relevant sections below. Please also note that many of the journals we cover continue to publish important EVD content which is threaded throughout this edition.

Important this week was a milestone WHO meeting on EVD vaccine candidates and new clinical trials to begin in the most affected countries shortly as reported below.

We also note that the WHO Situation Report below clarifies that the "100% goals" for 1 January 2015 were not met. We are not aware that these goals (or revised/additional goals) with a new date target have been announced.

<u>Ban Ki-moon on his priorities for 2015 - General Assembly, Informal meeting of the plenary - 8 Jan 2014</u> *Excerpt on Ebola*

Remarks by United Nations Secretary-General Ban Ki-moon at the informal meeting of the General Assembly on the Year Ahead.

Video: http://webtv.un.org/watch/ban-ki-moon-on-his-priorities-for-2015-general-assembly-informal-meeting-of-the-plenary/3978253934001

Text: http://www.un.org/sg/statements/index.asp?nid=8312

Excerpt on Ebola

...The outbreak of Ebola in West Africa has been a human tragedy and a setback for development in the hardest hit countries, and has highlighted the need for global vigilance and solidarity.

I thank the General Assembly for its unprecedentedly rapid action to establish UNMEER, the UN Mission for Ebola Emergency Response. The affected countries are beginning to see some improvements, thanks to their own mobilization and global support. Mali has made progress in controlling the virus, and we hope that Mali will be declared Ebola-free this month.

I have been especially moved by the deployment of health workers from many African countries and other parts of the world. But, Excellencies, we are still short of people and resources. As we strive to fill those gaps, we also need to address the wider impacts and to meet recovery needs.

We must also prepare for any possible new epidemic, wherever it may occur. Strengthening national health systems is a priority. International rapid response capacities must be improved. In that regard, I support the efforts of the World Health Organization led by Dr. Margaret Chan, to begin work on the way forward....

WHO: Ebola response roadmap - Situation report 7 January 2015

[Excerpt]
Summary

:: Reported case incidence continues to fluctuate in Guinea, with no identifiable downward trend. Ebola virus disease (EVD) continues to spread geographically within the country, with the prefecture of Fria reporting 2 confirmed cases for the first time. Case incidence has declined to

low levels in Liberia. There are signs that incidence has levelled off in Sierra Leone, although transmission remains intense in the west of the country.

- :: The UN Mission for Ebola Emergency Response (UNMEER) set twin targets of isolating and treating 100% of EVD cases, and conducting 100% of burials safely and with dignity by 1 January, 2015, in Guinea, Liberia, and Sierra Leone.
- :: Each of the intense-transmission countries has sufficient capacity to isolate and treat patients, with more than 2 treatment beds per reported confirmed and probable case. However, the uneven geographical distribution of beds and cases, and the under-reporting of cases, means that the UNMEER target of isolating and treating 100% of EVD cases is still not met in some areas. An increasing emphasis will be put on the rapid deployment of smaller treatment facilities to ensure that capacity is matched with demand in each area.
- :: Similarly, each country has sufficient capacity to bury all people known to have died from EVD, though the under-reporting of deaths means that the UNMEER target of 100% safe burial was not met.
- :: In addition to the two UNMMER targets, there are several other crucial aspects of the response, including rigorous contact tracing, access to laboratory services, and community engagement.
- :: Guinea, Liberia and Sierra Leone report that more than 90% of registered contacts are monitored, though the number of contacts traced per EVD case remains lower than expected in many districts. In areas where transmission has been driven down to low levels, rigorous contact tracing will be essential to break chains of transmission.
- :: There are currently 23 laboratories providing case-confirmation services in the three intense-transmission countries. Five more laboratories are planned in order to meet demand.
- :: Case fatality among hospitalized patients (calculated from all hospitalized patients with a reported definitive outcome) is approximately 60% in the three intense-transmission countries. :: A total of 820 health-care worker infections have been reported in the intense-transmission countries; there have been 488 deaths.
- :: Many elements of the response to the EVD outbreak, from safe burials to contact tracing, rely on actively engaging affected communities to take ownership of the response. UNICEF leads the community engagement arm of the EVD response. At present, 33 of 38 (87%) of districts in Guinea, 100% of districts in Liberia, and 57% (8 of 14) of districts in Sierra Leone have systems in place to monitor community engagement activities.

1. COUNTRIES WITH WIDESPREAD AND INTENSE TRANSMISSION

There have been in excess of 20,000 confirmed, probable, and suspected cases of EVD in Guinea, Liberia and Sierra Leone (table 1), with more than 8,000 deaths (deaths are under-reported).

A stratified analysis of cumulative confirmed and probable cases indicates that the number of cases in males and females is about the same (table 2). Compared with children (people aged 14 years and under), people aged 15 to 44 are three times more likely to be affected (33)

reported cases per 100 000 population, compared with 98 per 100,000 population). People aged 45 and over (125 reported cases per 100 000 population) are almost four times more likely to be affected than are children.

There have been 26 reported confirmed and probable cases per 100,000 population in Guinea, 206 cases per 100,000 population in Liberia, and 170 cases per 100,000 population in Sierra Leone...

WHO: Second high-level meeting on Ebola vaccines access and financing

Date: 8 January 2015 Place: Geneva, Switzerland About the meeting

On 8 January 2015, WHO will convene the second high-level meeting on Ebola vaccines access and financing. The meeting will review the current status of clinical trials of Ebola vaccines and plans for Phase II and Phase III efficacy trials.

Also on the agenda are discussion of funding mechanisms for potential Ebola vaccine introduction and the process for decision-making on introduction beyond Phase III trials. This meeting is a follow-up to the First high-level meeting on Ebola vaccines access and financing held on 23 October 2014.

Participants of the meeting

The meeting will be chaired by Professor Helen Rees, University of Witwatersrand and Co-Chair of the SAGE Ebola Vaccine Working Group. Participants include representatives from manufacturers and research institutions that are currently developing or testing Ebola candidate vaccines, government officials from the Ebola-affected and neighbouring countries, and nongovernmental organizations and partners.

Meeting documents

- Agenda of the meeting pdf, 266kb
- <u>List of participants</u> pdf, 120kb

WHO Director-General opens high-level meeting on Ebola vaccines

8 January 2015

Distinguished experts,

Good morning and welcome to this second high-level meeting on Ebola vaccines access and financing. I thank you again for giving us your expertise and your time.

I will be brief. You have given yourselves some very tight deadlines and are moving ahead quickly. In fact, what you are doing is unprecedented: compressing into a matter of months work that normally takes 2 to 4 years, yet with no compromise of international standards of safety and efficacy.

We are here to take stock, plan the next steps, and make sure that all partners are working in tandem. We all want the momentum and sense of urgency to continue. We want to spot potential bottlenecks early and iron out any difficulties that could slow things down. Even the highest ambitions become feasible with determination and good planning.

Previous experts agreed that vaccines will have an impact on the Ebola epidemic in any future scenario, whether worst-case or best-case. I see no indication that this view has changed. In terms of the dynamics of the outbreaks in Guinea, Liberia, and Sierra Leone, last year did not end with a best-case scenario. Too many health care workers are still getting infected, including nationals and doctors and nurses from foreign medical teams.

The situation in Liberia looks far more promising than it did in October and November, with cases showing a persistent decline and smaller geographical distribution. But transmission in Monrovia continues, with cases scattered throughout the city, making it difficult to identify distinct transmission chains. Many believe that the virus has moved from the cities into extremely remote rural areas, making it difficult to see what is really happening in Liberia.

Sierra Leone has now outstripped Liberia as the worst-affected country. Several hundred cases are being reported each week.

During the third week in December, Guinea reported nearly 160 confirmed cases, the highest weekly case incidence in the year-long history of the outbreak there.

The wide geographical dispersion of cases remains a problem. Whereas only 7 prefectures reported cases in October, that number had grown to 17 by mid-December. Ladies and gentlemen,

During this meeting, you will take a look at safety and immunogenicity data emerging from Phase 1 clinical trials of two candidate vaccines and review the status of other vaccines.

It is my understanding that no major safety signals have been reported to date. Trials of the Merck vaccine have restarted after a pause at the end of December.

You will look at vaccine pipelines and consider the plans of companies to extend the safety database during Phase 2 evaluation.

Critically important will be your discussion of preparations for Phase 3 efficacy trials in the three countries, using different trial designs that can take our knowledge base some big steps forward.

We will seek clarity on roles and responsibilities and how to coordinate the different actions. We also need some hard thinking about implementation challenges and how to overcome them. Financing and implementation of vaccination campaigns are covered in session 4.

You will hear from GAVI and others about planned investments and from WHO's experienced Ebola fighter, Jean-Marie Okwo-Bele.

Okwo will propose some triggers that can guide decisions about when and how to launch vaccination campaigns.

I think all of us have high expectations for the outcome of this meeting.

As a WHO staff member who has spent several months in Guinea recently observed, what people need most is hope.

They have watched families and communities torn apart by this virus for a year and are close to despair.

You can give them some of that hope.

Thank you.

WHO Press Releases

:: No Ebola cases detected in Iraq

6 January 2015 -- The Ministry of Health in Iraq, in collaboration with WHO, confirms that there is no suspected case of Ebola virus disease in Iraq as of 5 January 2015.

:: New UNMEER chief arrives in Liberia to assess Ebola response

6 January 2015 -- The new Head of UNMEER, Ismail Ould Cheikh Ahmed, arrived in Liberia as part of his first tour of the affected countries.

<u>Johnson & Johnson Announces Start of Phase 1 Clinical Trial of Ebola Vaccine</u>
<u>Regimen</u>

Company Has Produced More Than 400,000 Vaccine Regimens for Use in Large-Scale Clinical Trials by April 2015

NEW BRUNSWICK, N.J. – Jan. 6, 2015 – Johnson & Johnson (NYSE: JNJ) today announced the start of a Phase 1, first-in-human clinical trial of a preventive Ebola vaccine in development at its Janssen Pharmaceutical Companies. The trial is being led by the Oxford Vaccine Group, part of the University of Oxford Department of Paediatrics. Recruitment in the trial is underway, and the first volunteers have received their initial vaccine dose. Enrollment is expected to be completed by the end of January.

Johnson & Johnson also announced today that Janssen, in partnership with Bavarian Nordic A/S, has produced more than 400,000 regimens of the prime-boost vaccine for use in large-scale clinical trials by April 2015. A total of 2 million regimens will be available through the course of 2015, with the ability to quickly scale up to 5 million regimens, if required, over a 12-to 18-month period. This increased projection is an update to Janssen's previous goal of producing more than 1 million regimens by the end of 2015, with 250,000 regimens for broad application in clinical trials by May 2015.

"As a leader in the field of global health, we have a responsibility to act swiftly as Ebola continues to cause suffering among patients, families and health care workers in West Africa," said Alex Gorsky, Chairman and CEO of Johnson & Johnson.

Modelling by the London School of Hygiene and Tropical Medicine to advise the World Health Organization (WHO) indicates that to bring the epidemic under control, current projected demand for a preventive vaccine ranges from a minimum of 100,000 doses to protect frontline workers to a high-end of 12 million doses for large-scale adult vaccination in the three affected countries.

...The Phase 1, first-in-human study will evaluate the safety and tolerability of a prime-boost vaccine regimen, in which patients are first given a dose to prime the immune system, and then a boost intended to enhance the immune response over time. The immune response generated by the regimen will also be evaluated longer term. Different regimens combining the vaccine components or placebo will be studied in 72 healthy adult volunteers. Additional clinical studies are planned to begin in the United States later this month and soon after in Africa. Further details of the study are posted on clinicaltrials.gov.

In October 2014, Johnson & Johnson <u>announced</u> a commitment of up to \$200 million to accelerate and significantly expand production of an Ebola vaccine program in development at its Janssen Pharmaceutical Companies. The company is seeking to share the financial risk of these vaccine and development clinical trial costs by pursuing governmental and non-governmental funding sources. The vaccine regimen, which was discovered in a collaborative research program with the National Institutes of Health (NIH), uses a prime-boost combination of two components that are based on AdVac® technology from Crucell Holland B.V., one of the Janssen Pharmaceutical Companies, and the MVA-BN® technology from Bavarian Nordic, a biotechnology company based in Denmark.

The Crucell Holland B.V. program received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, under Contract Numbers HHSN272200800056C, and HHSN272201000006I and HHSN272201200003I, respectively. Preclinical experiments of the prime-boost vaccine regimen conducted by the NIH demonstrated that when both vaccines were administered two months apart, complete protection from death due to Ebola was achieved against the Kikwit Zaire strain, which is similar to the virus that is the cause of the current outbreak in West Africa. The research collaboration for a monovalent vaccine targeting the Zaire strain of the Ebola virus is part of an ongoing

development program for a multivalent vaccine against all virus strains that cause disease in humans, including Ebola and Marburg viruses based on the Ad26 and Ad35 vectors.

The Johnson & Johnson Family of Companies continues to closely collaborate with WHO, NIAID and the European Commission, as well as other key stakeholders, governments, public health authorities, and non-governmental organizations on the clinical testing, development, production and distribution of the vaccine...

clinicaltrials.gov :: A Safety and Immunogenicity Study of Heterologous Prime-Boost Ebola Vaccine Regimens in Healthy Participants

Merck-NewLink Ebola vaccine trial resumes at lower dose -Geneva hospital

Reuters | 5 January 2015

Excerpt

The clinical trial of an Ebola vaccine developed by Merck and NewLink resumed on Monday at a lower dose after a pause to assess complaints of joint pains in some volunteers, the University of Geneva hospital said...

...The Geneva hospital announced on Dec. 11 that its vaccine trial had been suspended as a precautionary measure after four patients complained of joint pains. On Monday, the hospital said 10 of 59 volunteers who received the vaccine had felt pains in their joints "similar to rheumatism" after some two weeks, but these symptoms had disappeared rapidly without any treatment.

Swissmedic, the Swiss regulatory agency, and ethics and safety committees have approved the resumption of the trial at a lower dose, the hospital said in a statement.

"The second part of this clinical trial will now test a dose of 300,000 vaccine particles, which should be better tolerated by volunteers and will hopefully trigger the production of enough antibodies," it said, noting that the initial phase had 10 million to 50 million vaccine particles.

"Fortunately", it said, the Merck-NewLink candidate vaccine "seems able to induce the production of antibodies at lower doses than those previously used" in the Geneva trial. Vaccinations have now resumed for the last 56 volunteers, who will receive either a low dose of the vaccine or a placebo, by groups of 15 each week through January, it said...

UNMEER Watch [to 10 January 2015]

:: 06 Jan 2015 - New UNMEER Chief Arrives in Liberia to Assess Ebola Response

UNICEF Watch [to 10 January 2015]

:: UNICEF helps restart measles immunizations in Ebola-hit countries

ENEVA/DAKAR/CONAKRY/FREETOWN/MONROVIA, 9 January 2015 – UNICEF is helping governments and communities restart stalled immunizations amid a surge in measles cases in Ebola-affected countries, where health systems are overwhelmed and tens of thousands of children are left vulnerable to deadly diseases.

"Measles is a major killer of children that can easily be stopped through a safe and effective vaccine," said Manuel Fontaine, UNICEF Regional Director for West and Central Africa. "But immunization rates have dropped significantly, further threatening children's lives."

In Guinea, where a measles outbreak was declared in early 2014 - prior to Ebola - the number of confirmed measles cases increased almost fourfold, from 59 between January and December 2013 to 215 for the same period in 2014, according to WHO. In Sierra Leone, the

figure tripled from 13 to 39 over the same period.

In Liberia, which had reported no measles in 2013, four cases have been confirmed in Lofa County, one of the areas hardest hit by Ebola.

The increase in cases of measles – a highly contagious disease - is of particular concern as a drop in immunization coverage rates has left children vulnerable at a time when measles transmission traditionally peaks in West Africa, between December and March...

...As vaccinators venture out to provide lifesaving vaccines, which in many cases are long overdue, they also help with the control of the Ebola outbreak. In compliance with infection prevention and control (IPC) procedures and WHO guidelines on immunization in the context of an Ebola outbreak, UNICEF is providing not only vaccines, but also kits that include gloves and infrared thermometers for vaccinators. Vaccinators are being trained on infection prevention and control measures, supervision during immunization activities, and on how to conduct outreach sessions in areas which have not reported an Ebola case for 42 days...

CDC/MMWR Watch [to 10 January 2015]

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

:: <u>Enhanced Airport Entry Screening To End for Travelers from Mali to the United States - Press Release</u> - Monday, January 5, 2015

:: MMWR Weekly, January 9, 2015 / Vol. 63 / No. 53

- <u>Notes from the Field: Acute Flaccid Myelitis Among Persons Aged ≤21 Years United States,</u> August 1–November 13, 2014
- <u>Notes from the Field: Occupationally Acquired HIV Infection Among Health Care Workers United States, 1985–2013</u>

MSF/Médecins Sans Frontières [to 10 January 2015]

:: Oxford University Begins Trial of Possible Ebola Treatment at MSF Treatment Center in Monrovia

January 07, 2015

A clinical trial of a possible treatment for Ebola began on January 1, 2015, at ELWA 3, the Doctors Without Borders/Médecins Sans Frontières (MSF) Ebola Management Center in Monrovia, Liberia. Led by Oxford University, the trial aims to determine if the antiviral drug brincidofovir is a safe and effective treatment for Ebola. While MSF hopes that brincidofovir might help patients survive infection, it is still not sure whether this will be the case.

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WHO & Regionals [to 10 January 2015]

:: 136th WHO Executive Board session

26 January-3 February 2015

:: WHO grants approval for safe, effective meningitis A vaccine for infants

9 January 2015

WHO has opened the door to routine immunization of infants in Africa by approving for use an innovative and affordable vaccine that has all but rid the meningitis belt of a major cause of deadly epidemics. Since its introduction in Africa in December 2010, MenAfriVac has had an immediate and dramatic impact in breaking the cycle of meningitis A epidemics, leading the safe, effective technology to be approved by WHO through its prequalification process for use in infants, and paving the way for protecting millions more children at risk of the deadly disease. Read the news release on meningitis A vaccine

:: Global Alert and Response (GAR): Disease Outbreak News (DONs)

- Ebola virus disease – United Kingdom 30 December 2014

On 29 December 2014, WHO was notified by the National IHR Focal Point for the United Kingdom of a laboratory-confirmed case of Ebola Virus Disease (EVD). This is the first EVD case to be detected on UK soil.

- 5 January 2015 - <u>Middle East respiratory syndrome coronavirus (MERS-CoV) – Jordan</u> On 25 December 2014, the National IHR Focal Point of Jordan notified WHO of 1 additional case of Middle East respiratory syndrome coronavirus (MERS-CoV) infection.

Contact tracing of household contacts and healthcare contacts is ongoing for this case.

The National IHR Focal Point for the Kingdom of Saudi Arabia also notified WHO of the death of 3 previously reported MERS-CoV cases.*

Globally, the WHO has been notified of 945 laboratory-confirmed cases of infection with MERS-CoV, including at least 348 related deaths.

- :: The <u>Weekly Epidemiological Record (WER) for 9 January 2015</u>, vol. 90, 1/2 (pp. 1–8) includes:
- Immunization and Vaccine related Implementation Research Advisory Committee (IVIR-AC): summary of conclusions and recommendations 17–19 September 2014 meeting

WHO Regional Offices

WHO African Region AFRO

Press Releases

:: Sexual and intimate partner violence affects millions in Africa

Brazzaville, 5 January 2015 – In the African Region, one in five girls have been sexually abused during childhood, with estimates from some countries placing that proportion closer to one in three. This startling statistic is highlighted in the newly released Global status report on violence prevention 2014.

WHO Region of the Americas PAHO

:: PANAFTOSA marks three years without foot-and-mouth disease outbreaks in the Americas Rio de Janeiro, 5 January 2015 (PANAFTOSA) - January 2015 marks the third year in a row in which the Region of the Americas has had no outbreak of foot-and-mouth disease (FMD), a highly contagious animal disease that can have a devastating impact on livestock. In marking the achievement, the Pan American Foot-and-Mouth Disease Center (PANAFTOSA), a specialized technical center of the Pan American Health Organization (PAHO), noted the importance of the investments and hard work of the two organizations' member countries. Foot-and-mouth disease (FMD) is a highly contagious viral disease that primarily affects cloven-hooved livestock and wildlife. Outbreaks can severely disrupt livestock production and trade, causing major economic losses and threatening food security. FMD is not related to hand, foot and mouth disease, a condition seen only in humans, and is not considered a public health problem, as human cases are extremely rare...

WHO South-East Asia Region SEARO

No new digest content identified.

WHO European Region EURO

- :: United Kingdom Ebola case: tracing of airline passengers completed 10-01-2015
- :: Kyrgyz initiatives help reduce preventable child mortality 08-01-2015

WHO Eastern Mediterranean Region EMRO

No new digest content identified.

WHO Western Pacific Region

No new digest content identified.

BMGF - Gates Foundation Watch [to 10 January 2015]

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

New Collection by More Than 30 World-Renowned Artists Illustrates the Global Impact of Vaccines

The Art of Saving a Life Project Features the Work of Angélique Kidjo, Chimamanda Ngozi Adichie, GMB Akash, Sophie Blackall, Thomas Ganter, Vik Muniz, Alexia Sinclair and Others, and Debuts at Critical Moment for Global Vaccine Advocacy

SEATTLE (January 7, 2015) — The Bill & Melinda Gates Foundation today introduced The Art of Saving a Life project, a new initiative that brings together more than 30 world-renowned musicians, writers, filmmakers, painters, sculptors and photographers to demonstrate how vaccines continue to positively change the course of history.

The Art of Saving a Life is designed to support the critical work of <u>Gavi, the Vaccine Alliance</u> by spurring conversations about the value of vaccines. On January 27 in Berlin, German Chancellor Angela Merkel will host a high-level event seeking to mobilize funding for Gavi to help reach an additional 300 million children with life-saving vaccines by 2020. The conference will bring together world leaders, nongovernmental organizations, the private sector and other partners who will show their support for Gavi, and will feature select pieces of The Art of Saving a Life artwork.

"From sculptures to paintings, from digital animations to music, artists have been inspired to capture the amazing power of vaccines," said Gavi CEO Dr. Seth Berkley. "I'm looking forward to seeing a large part of this work in Berlin, where we will be calling on global leaders to stand together and pledge the necessary funds to immunize 300 million children by 2020, which will prevent up to 6 million deaths. This is a remarkable mix of both the art and science of saving a life."...

IVI Watch [to 10 January 2015]

http://www.ivi.org/web/www/home

SK Chemicals staff's interview with SBS TV about collaboration with IVI and BMGF [Undated]

An interview featuring Dr. KIM Hoon, head of SK Chemicals' life-science lab, was on SBS? CNBC TV, a Korean cable station dedicated to business and market, including comments about collaboration with IVI and BMGF. Here are some highlights from the interview.

Q. We hear that SK Chemicals is jointly developing a typhoid fever vaccine.

A. Yes. That's right.

Q. Notably, SK Chemicals received funding from the Bill & Melinda Gates Foundation, right?

A. SK Chemicals is committed to its mission of improving the health of human beings. The joint development of typhoid vaccine with IVI is very significant in our efforts to achieve this mission.

The fact that IVI picked SK as a partner, and that the Gates provided 5.4 billion won fund is testament to that SK's vaccine development and production capacities has reached the global level.

By developing a more improved vaccine, SK Chemicals will contribute to saving the precious lives of children in developing countries.

Phase 1 clinical trials will start late this year, and after completion of clinical trials, the vaccine will be produced at SK Chemicals' plant in Andong, and will be supplied through international organizations.

Q: Could support from the Gates Foundation and cooperation with IVI mean that securing financial profitability is a challenge?

A. It is not a matter of profitability. The shared goal of the two organizations is to improve the health of humanity through vaccines. SK Chemicals also shares this goal.

Q: We hear that prequalification (PQ) is key to this endeavor. Would it be possible to achieve?

A. The new vaccine will likely provide long-term protection, and protection in young children under age 2, which conventional typhoid vaccines do not.

To save children's lives in developing countries, entering the global market is essential. Due support from IVI, and the Food and Drug Safety Ministry of Korea, and to SK Chemicals' world-class capacity, we expect development will be completed in line with schedule.

To hear the full interview please click here:

http://sbscnbc.sbs.co.kr/read.jsp?pmArticleId=10000712198

European Vaccine Initiative Watch [to 10 January 2015]

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

:: Exciting career opportunity as Vaccine Management Assistant at EVI

09 January 2015

Deadline for applications 15 February 2015 17:00 CET. <u>Download PD-version</u> EVI has an exciting career opportunity for junior and motivated individual to join the

organisation in an eighteen month full time position as Vaccine Management Assistant (VMA) for a phase I vaccine clinical trial.

:: News London School of Hygiene & Tropical Medicine is offering a short course 07 January 2015

Epidemiological evaluation of vaccines: efficacy, safety and policy

The overall aim of this short course is to provide an understanding of the methods used in the evaluation of vaccines, from early human trials through to assessment of population impact and policy.

Industry Watch [to 10 January 2015]

:: Pfizer Acquires Redvax GmbH

Acquisition Provides Pfizer with a Preclinical CMV Vaccine Candidate January 05, 2015

NEW YORK--(Pfizer Inc. today announced that it has acquired a controlling interest in Redvax GmbH, a spin-off from Redbiotec AG, a privately held Swiss biopharmaceutical company, based in Zurich-Schlieren. This transaction provides access to a preclinical human cytomegalovirus (CMV) vaccine candidate, as well as intellectual property and a technology platform related to a second, undisclosed vaccine program...

Global Fund Watch [to 10 January 2015]

http://www.theglobalfund.org/en/mediacenter/

Press releases

Zambia and Global Fund Sign \$234 Million in New Grants

09 January 2015

LUSAKA, Zambia - The Government of the Republic of Zambia, the Churches Health Association of Zambia, and the Global Fund today reaffirmed their partnership, signing four new grants worth US\$234 million to fight HIV, TB and malaria in Zambia.

The financial resources provided through the Global Fund come from many donors, represented today by the European Union, Sweden, the United Kingdom and the United States. Beyond finances, the grant agreements embody solidarity with the people of Zambia, supporting health initiatives through partnership with UNAIDS, UNICEF, UNDP, UNFPA, WFP and WHO, (RED), ONE and the Bill & Melinda Gates Foundation and others.

The HIV/TB grants expand availability of anti-retroviral medication for people living with both HIV and tuberculosis from 80 percent in 2013 to a target of 90 percent by 2017. Zambia will also intensify TB case detection among key populations, children, prisoners and other groups identified by Zambia's TB survey, and enhance HIV/TB integration.

The malaria grants aim to sustain universal coverage of treatment and increase household use of mosquito nets from 49 percent in 2012 to 85 percent by 2017. The number of malaria cases and deaths is expected to halve in 2017 compared with 2013. The grants also strengthen community and health systems...

GAVI Watch [to 10 January 2015]

http://www.gavialliance.org/library/news/press-releases/ No new digest content identified.

IAVI Watch [10 January 2015]

No new digest content identified.

PATH Watch [to 10 January 2015]

http://www.path.org/news/

No new digest content identified.

Sabin Vaccine Institute Watch [to 10 January 2015]

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

No new digest content identified.

NIH Watch [to 10 January 2015]

http://www.nih.gov/news/index.html

No new digest content identified.

FDA Watch [to 10 January 2015]

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

European Medicines Agency Watch [to 10 January 2015]

http://www.ema.europa.eu/ema/ No new digest content identified.

DCVMN / PhRMA / EFPIA / IFPMA / BIO Watch [to 10 January 2015]

No new digest content identified.

<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

No new digest content identified.

Journal Watch

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

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

The American Journal of Bioethics

<u>Volume 15</u>, Issue 1, 2015 <u>http://www.tandfonline.com/toc/uajb20/current</u> [No issue; No relevant content]

American Journal of Infection Control

January 2015 Volume 43, Issue 1, p1-98 http://www.ajicjournal.org/current [No issue; No relevant content]

American Journal of Preventive Medicine

January 2015 Volume 48, Issue 1, p1-120 http://www.ajpmonline.org/current [Reviewed earlier]

American Journal of Public Health

Volume 105, Issue 1 (January 2015) http://ajph.aphapublications.org/toc/ajph/current [Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

January 2015; 92 (1)

http://www.ajtmh.org/content/current

Fditorial

Expanding the Toolbox in Pursuit of a Strain Transcendent Malaria Vaccine

Anne E.P. Frosch and Chandy C. John

Am J Trop Med Hyg 2015 92:1-2; Published online November 24, 2014, doi:10.4269/ajtmh.14-0662

[No abstract]

Environmental Surveillance for Toxigenic Vibrio cholerae in Surface Waters of Haiti

Am J Trop Med Hyg 2015 92:118-125; Published online November 10, 2014, doi:10.4269/ajtmh.13-0601

Amy M. Kahler, Bradd J. Haley, Arlene Chen, Bonnie J. Mull, Cheryl L. Tarr, Maryann Turnsek, Lee S. Katz, Michael S. Humphrys, Gordana Derado, Nicole Freeman, Jacques Boncy, Rita R. Colwell, Anwar Huq, and Vincent R. Hill

Abstract

Epidemic cholera was reported in Haiti in 2010, with no information available on the occurrence or geographic distribution of toxigenic Vibrio cholerae in Haitian waters. In a series of field visits conducted in Haiti between 2011 and 2013, water and plankton samples were collected at 19 sites. Vibrio cholerae was detected using culture, polymerase chain reaction, and direct viable count methods (DFA-DVC). Cholera toxin genes were detected by polymerase chain reaction in broth enrichments of samples collected in all visits except March 2012. Toxigenic V. cholerae was isolated from river water in 2011 and 2013. Whole genome sequencing revealed that these isolates were a match to the outbreak strain. The DFA-DVC tests were positive for V. cholerae O1 in plankton samples collected from multiple sites. Results of this survey show that toxigenic V. cholerae could be recovered from surface waters in Haiti more than 2 years after the onset of the epidemic.

The Development and Implementation of a Competency-Based Curriculum for Training in Global Health Research

<u>Thanh G. N. Ton, Sophia P. Gladding, Joseph R. Zunt, Chandy John, Vivek R. Nerurkar, Cheryl A. Moyer, Nicole Hobbs, Molly McCoy and Joseph C. Kolars*</u>

Author Affiliations

Departments of Neurology and Global Health, University of Washington, Seattle, Washington; Department of Pediatrics, University of Minnesota, Minnesota; Department of

Medicine (Infectious Disease), University of Washington, Seattle, Washington; Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawaii at Manoa, Honolulu, Hawaii; Global Research, Education and Collaboration in Health (REACH) and Departments of Learning Health Sciences and Internal Medicine, University of Michigan, Ann Arbor, Michigan Abstract

The Fogarty International Center (FIC) Global Health Fellows Program provides trainees with the opportunity to develop research skills through a mentored research experience, increase their content expertise, and better understand trends in global health research, funding organizations, and pathways to generate support. The Northern Pacific Global Health Fellows Research and Training Consortium, which hosts one of the FIC Global Health Programs, sought to enhance research training by developing, implementing, and evaluating a competency-based curriculum that uses a modular, asynchronous, web-based format. The curriculum has 8 core competencies, 36 learning objectives, and 58 assignments. Nineteen trainees completed their 11-month fellowship, engaged in the curriculum, and provided pre- and post-fellowship self-assessments. Self-assessed scores significantly improved for all competencies. Trainees identified the curriculum as one of the strengths of the program. This competency-based curriculum represents a first step toward creating a framework of global health research competencies on which further efforts could be based.

Annals of Internal Medicine

6 January 2015, Vol. 162. No. 1

http://annals.org/issue.aspx

Original Research | 6 January 2015

Effect of Ebola Progression on Transmission and Control in Liberia FREE

Dan Yamin, PhD*; Shai Gertler*; Martial L. Ndeffo-Mbah, PhD*; Laura A. Skrip, MPH; Mosoka Fallah, PhD; Tolbert G. Nyenswah, MPH; Frederick L. Altice, MD, MA; and Alison P. Galvani, PhD [+] Article and Author Information

Ann Intern Med. 2015;162(1):11-17. doi:10.7326/M14-2255

* Dr. Yamin, Mr. Gertler, and Dr. Ndeffo-Mbah contributed equally to this work. *Abstract*

Background: The Ebola outbreak that is sweeping across West Africa is the largest, most volatile, and deadliest Ebola epidemic ever recorded. Liberia is the most profoundly affected country, with more than 3500 infections and 2000 deaths recorded in the past 3 months. Objective: To evaluate the contribution of disease progression and case fatality on transmission and to examine the potential for targeted interventions to eliminate the disease.

Design: Stochastic transmission model that integrates epidemiologic and clinical data on incidence and case fatality, daily viral load among survivors and nonsurvivors evaluated on the basis of the 2000–2001 outbreak in Uganda, and primary data on contacts of patients with Ebola in Liberia.

Setting: Montserrado County, Liberia, July to September 2014.

Measurements: Ebola incidence and case-fatality records from 2014 Liberian Ministry of Health and Social Welfare.

Results: The average number of secondary infections generated throughout the entire infectious period of a single infected case, R, was estimated as 1.73 (95% CI, 1.66 to 1.83). There was substantial stratification between survivors (RSurvivors), for whom the estimate was 0.66 (CI, 0.10 to 1.69), and nonsurvivors (RNonsurvivors), for whom the estimate was 2.36 (CI,

1.72 to 2.80). The nonsurvivors had the highest risk for transmitting the virus later in the course of disease progression. Consequently, the isolation of 75% of infected individuals in critical condition within 4 days from symptom onset has a high chance of eliminating the disease.

Limitation: Projections are based on the initial dynamics of the epidemic, which may change as the outbreak and interventions evolve.

Conclusion: These results underscore the importance of isolating the most severely ill patients with Ebola within the first few days of their symptomatic phase.

Primary Funding Source: National Institutes of Health.

The Potential Ebola—Infected Patient in the Ambulatory Care Setting: Preparing for the Worst Without Compromising Care FREE

Henry M. Wu, MD; Jessica K. Fairley, MD; James Steinberg, MD; and Phyllis Kozarsky, MD Caring for Patients With Ebola: A Challenge in Any Care Facility FREE

Mark G. Kortepeter, MD, MPH; Philip W. Smith, MD; Angela Hewlett, MD; and Theodore J. Cieslak, MD

BMC Health Services Research

http://www.biomedcentral.com/bmchealthservres/content (Accessed 10 January 2015) [No new relevant content]

BMC Infectious Diseases

http://www.biomedcentral.com/bmcinfectdis/content (Accessed 10 January 2015) [No new relevant content]

BMC Medical Ethics

(Accessed 10 January 2015)
http://www.biomedcentral.com/bmcmedethics/content
[No new relevant content]

BMC Public Health

(Accessed 10 January 2015)
http://www.biomedcentral.com/bmcpublichealth/content
[No new relevant content]

BMC Research Notes

(Accessed 10 January 2015)
http://www.biomedcentral.com/bmcresnotes/content
[No new relevant content]

British Medical Journal

10 January 2015(vol 350, issue 7990)

http://www.bmj.com/content/350/7990

Editorials

Two or three doses of human papillomavirus vaccine?

Julia Brotherton, medical director

Author affiliations

BMJ 2015; 350 doi: http://dx.doi.org/10.1136/bmj.g7778 (Published 07 January 2015) Cite this as: BMJ 2015;350:g7778

Switching to two doses looks feasible, but only with careful monitoring

Human papillomavirus (HPV) vaccines have the potential to prevent the considerable morbidity and mortality caused by oncogenic HPV types. In the eight years since the vaccines were first licensed, we have seen remarkable reductions in genital warts, HPV infections, and pre-cancerous cervical lesions in vaccinated populations. 1 2 3 4 5 6 7 8 However, achieving high coverage with three doses of vaccine is challenging in many populations, and the cost of the vaccine has kept it out of reach for many countries. In a linked paper (doi:10.1136/bmj.g7584), Jit and colleagues explore, through modelling, the potential cost effectiveness of a two dose HPV vaccination schedule.9

Both the bivalent and quadrivalent HPV vaccines were initially registered for use as three dose courses given over six months, using the model of subunit vaccines for which multiple doses are needed to generate a sufficient immune response. However, HPV vaccines are notably immunogenic, producing very high and durable antibody responses, and the virus-like particle structure of the vaccines, with their repetitive antigen display, may be stimulating immunity that is more akin to the response generated by viral infections or live vaccines.10 ...

Research

<u>Comparison of two dose and three dose human papillomavirus vaccine schedules:</u> <u>cost effectiveness analysis based on transmission model</u>

Mark Jit, mathematical modeller and health economist $\underline{12}$, Marc Brisson, associate professor of mathematical epidemiology and health economics $\underline{345}$, Jean-François Laprise, mathematical modeller $\underline{3}$, Yoon Hong Choi, mathematical modeller $\underline{16}$

Author affiliations

BMJ 2015; 350 doi: http://dx.doi.org/10.1136/bmj.g7584 (Published 07 January 2015) Cite this as: BMJ 2015;350:g7584

Abstract Objective

To investigate the incremental cost effectiveness of two dose human papillomavirus vaccination and of additionally giving a third dose.

Design

Cost effectiveness study based on a transmission dynamic model of human papillomavirus vaccination. Two dose schedules for bivalent or quadrivalent human papillomavirus vaccines were assumed to provide 10, 20, or 30 years' vaccine type protection and cross protection or lifelong vaccine type protection without cross protection. Three dose schedules were assumed to give lifelong vaccine type and cross protection.

Settina

United Kingdom.

Population

Males and females aged 12-74 years.

Interventions

No, two, or three doses of human papillomavirus vaccine given routinely to 12 year old girls, with an initial catch-up campaign to 18 years.

Main outcome measure

Costs (from the healthcare provider's perspective), health related utilities, and incremental cost effectiveness ratios.

Results

Giving at least two doses of vaccine seems to be highly cost effective across the entire range of scenarios considered at the quadrivalent vaccine list price of £86.50 (\in 109.23; \$136.00) per dose. If two doses give only 10 years' protection but adding a third dose extends this to lifetime protection, then the third dose also seems to be cost effective at £86.50 per dose (median incremental cost effectiveness ratio £17 000, interquartile range £11 700-£25 800). If two doses protect for more than 20 years, then the third dose will have to be priced substantially lower (median threshold price £31, interquartile range £28-£35) to be cost effective. Results are similar for a bivalent vaccine priced at £80.50 per dose and when the same scenarios are explored by parameterising a Canadian model (HPV-ADVISE) with economic data from the United Kingdom.

Conclusions

Two dose human papillomavirus vaccine schedules are likely to be the most cost effective option provided protection lasts for at least 20 years. As the precise duration of two dose schedules may not be known for decades, cohorts given two doses should be closely monitored

Bulletin of the World Health Organization

Volume 93, Number 1, January 2015, 1-64 http://www.who.int/bulletin/volumes/93/1/en/ [Reviewed earlier]

Clinical Infectious Diseases (CID)

Volume 60 Issue 2 January 15, 2015 http://cid.oxfordjournals.org/content/current [Reviewed earlier]

Clinical Therapeutics

Volume 36, Issue 12, p1865-2140 December 2014 http://www.clinicaltherapeutics.com/current [Reviewed earlier]

Complexity

November/December 2014 Volume 20, Issue 2 Pages fmi–fmi, 1–81 http://onlinelibrary.wiley.com/doi/10.1002/cplx.v20.2/issuetoc [Reviewed earlier]

Conflict and Health

[Accessed 10 January 2015]

[No new relevant content]

Contemporary Clinical Trials

Volume 41, In Progress (March 2015)

<u>Immunogenicity and safety of measles—mumps—rubella vaccine delivered by disposable-syringe jet injector in healthy Brazilian infants: A randomized non-inferiority study</u>

Original Research Article

Pages 1-8

Reinaldo de Menezes Martins, Birute Curran, Maria de Lourdes Sousa Maia, Maria das Graças Tavares Ribeiro, Luiz Antonio Bastos Camacho, Marcos da Silva Freire, Anna Maya Yoshida Yamamura, Marilda Mendonça Siqueira, Maria Cristina F. Lemos, Elizabeth Maciel de Albuquerque, Vanessa dos Reis von Doellinger, Akira Homma, Laura Saganic, Courtney Jarrahian, Michael Royals, Darin Zehrung

- Abstract

This study aimed to determine if immunogenicity to measles—mumps—rubella vaccine delivered to infants via a disposable-syringe jet injector (DSJI) was non-inferior to that administered by needle and syringe (NS). Vaccination safety was evaluated, as were the use, performance, and acceptability of each delivery method. The DSJI was the PharmaJet® 2009 generation-1 device (G1) and the vaccine was measles-mumps-rubella vaccine from Bio-Manguinhos. Five hundred eighty-two healthy Brazilian infants were randomized to receive vaccine via G1 or NS. Seroconversion rates against measles and mumps viruses in the G1 treatment group did not meet non-inferiority criteria when compared with the NS group; however, responses in the G1 group to rubella virus were non-inferior to those of NS vaccinees. Most adverse events were mild or moderate. Crying after injection was more frequent in the NS group, and local skin reactions were more common in the G1 group. Five serious adverse events were judged causally unrelated to treatment and all resolved. Parents/guardians expressed a strong preference for G1 over NS for their children. Vaccinators found the G1 easy to use but noted incomplete vaccine delivery in some cases. Although the G1 has been superseded by an updated device, our results are important for the continued improvement and evaluation of DSJIs, which have the potential to overcome many of the challenges and risks associated with needle-based injections worldwide. Recommendations for future DSJI clinical studies include rigorous training of vaccinators, quantitative measurement of wetness on the skin following injection, and regular monitoring of device and vaccinator performance.

Cost Effectiveness and Resource Allocation

(Accessed 10 January 2015)
http://www.resource-allocation.com/
[No new relevant content]

Current Opinion in Infectious Diseases

February 2015 - Volume 28 - Issue 1 pp: v-vi,1-116 http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx **Ebola virus as a sexually transmitted infection** Rogstad, Karen E.; Tunbridge, Anne *Abstract*

Purpose of review

The ongoing Ebola virus epidemic in West Africa is a major global health challenge. The main mode of transmission is through contact with bodily fluids and skin of those infected or who have died. This review was undertaken to consider the evidence for transmission by contact with bodily fluids occurring through sexual activity.

Recent findings

No cases in the previous 20 outbreaks or the current outbreak in West Africa have been shown to be sexually transmitted, although other types of viral haemorrhagic fever have had sexual transmission implicated. Ebola virus is found in sites and fluids associated with sexual activity but this occurs at different stages of the disease. Persistence in the convalescent period occurs in rectum, vagina and semen, with persistence in semen being longest of up to at least 101 days. Recommendations based on this data are that those recovering from Ebola virus disease should abstain from all sexual intercourse, or if this is not possible, use condoms, for 3 months after the onset of symptoms.

Summary

There is theoretical plausibility for sexual transmission of Ebola virus but there has been no evidence of this occurring. Further research is needed to consider if sexual activity contributes to the epidemic in order to inform individuals with regard to avoiding acquisition or transmission by those recovering from Ebola virus disease.

Developing World Bioethics

December 2014 Volume 14, Issue 3 Pages ii–iii, 111–167 http://onlinelibrary.wiley.com/doi/10.1111/dewb.2014.14.issue-3/issuetoc [Reviewed earlier]

Development in Practice

<u>Volume 25</u>, Issue 1, 2015 <u>http://www.tandfonline.com/toc/cdip20/current</u> [Reviewed earlier]

Emerging Infectious Diseases

Volume 21, Number 1—January 2015

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

<u>Continuing Effectiveness of Serogroup A Meningococcal Conjugate Vaccine, Chad, 2013 PDF Version [PDF - 499 KB - 4 pages]</u>

K. Gamougam et al.

Epidemics

Volume 9, <u>In Progress</u> (December 2014) <u>http://www.sciencedirect.com/science/journal/17554365</u> [Reviewed earlier]

Epidemiology and Infection

Volume 143 - Issue 02 - January 2015 http://journals.cambridge.org/action/displayIssue?jid=HYG&tab=currentissue [Reviewed earlier]

The European Journal of Public Health

Volume 24, Issue 6, 01 December 2014 http://eurpub.oxfordjournals.org/content/24/6 [Reviewed earlier]

Eurosurveillance

Volume 20, Issue 1, 08 January 2015

http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678
Rapid communications

<u>First secondary case of Ebola outside Africa: epidemiological characteristics and contact monitoring, Spain, September to November 2014</u>

by MA Lópaz, C Amela, M Ordobas, MF Domínguez-Berjón, C Álvarez, M Martínez, MJ Sierra, F Simon, JM Jansá, D Plachouras, J Astray, Working group of Ebola outbreak investigation team of Madrid

EbolaTracks: an automated SMS system for monitoring persons potentially exposed to Ebola virus disease

by LE Tracey, AK Regan, PK Armstrong, GK Dowse, PV Effler *Research articles*

Assessing the risk of measles resurgence in a highly vaccinated population: Belgium anno 2013

by N Hens, S Abrams, E Santermans, H Theeten, N Goeyvaerts, T Lernout, E Leuridan, K Van Kerckhove, H Goossens, P Van Damme, P Beutels

<u>European Union SHIPSAN ACT Joint Action: Preparedness for the response to Ebola virus disease in the maritime transport sector</u>

by VA Mouchtouri, G Nichols

Global Health: Science and Practice (GHSP)

December 2014 | Volume 2 | Issue 4 http://www.ghspjournal.org/content/current [Reviewed earlier]

Global Health Governance

[Accessed 10 January 2015] http://blogs.shu.edu/ghg/category/complete-issues/summer-2013/ [No new relevant content]

Global Public Health

Volume 10, Issue 1, 2015 http://www.tandfonline.com/toc/rgph20/10/1#.VI0Y33tW_4U [Reviewed earlier]

Globalization and Health

[Accessed 10 January 2015]
http://www.globalizationandhealth.com/
[No new relevant content]

Health Affairs

January 2015; Volume 34, Issue 1 http://content.healthaffairs.org/content/current Variety Issue [New issue; No relevant content]

Health and Human Rights

Volume 16, Issue 2 December 2014 http://www.hhrjournal.org/volume-16-issue-2/ Papers in Press: Special Issue on Health Rights Litigation
[Reviewed earlier]

Health Economics, Policy and Law

Volume 10 - Special Issue 01 January 2015 http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue SPECIAL ISSUE: Global Financial Crisis, Health and Health Care [Reviewed earlier]

Health Policy and Planning

Volume 29 Issue 8 December 2014 http://heapol.oxfordjournals.org/content/current [Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content [Accessed 10 January 2015] [No new relevant content]

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)

Volume 10, Issue 9, 2014

http://www.landesbioscience.com/journals/vaccines/toc/volume/10/issue/9/

Special Issue on Vaccine Acceptance; Key focus on HPV vaccine uptake and maternal immunization
[Reviewed earlier]

Infectious Agents and Cancer

[Accessed 10 January 2015] http://www.infectagentscancer.com/content [No new relevant content]

Infectious Diseases of Poverty

[Accessed 10 January 2015] http://www.idpjournal.com/content Letter to the Editor

Are surveillance response systems enough to effectively combat and contain the **Ebola outbreak?**

Viroj Wiwanitkit, Ernest Tambo, Emmanuel Chidiebere Ugwu, Jeane Yonkeu Ngogang and Xiao-Nong Zhou

Infectious Diseases of Poverty 2015, 4:7 doi:10.1186/2049-9957-4-7

Published: 9 January 2015

Abstract (provisional)

The epidemic of the Ebola virus infection in West Africa in 2014 has become a worldwide concern. Due to the nature of the disease, which has an extremely high mortality potential, this outbreak has received much attention from researchers and public health workers. An article entitled "Need of surveillance response systems to combat Ebola outbreaks and other emerging infectious diseases in African countries," published in the journal Infectious Diseases of Poverty in August 2014, concluded that a good surveillance system to monitor disease transmission dynamics is essential and needs to be implemented to combat the outbreak. Issues regarding the limitation of the passive surveillance system have been raised by Professor Viroj Wiwanitkit, who emphasizes the need for an active disease detection system such as mass screening in this letter to editor. The different function between passive and active surveillance system in combating the disease outbreak has been agreed upon by Ernest Tambo et al. There have also been discussions between Wiwanitkit and Tambo et al. on the following issues: (i) the extreme resource limitations in outbreak areas, (ii) new technology to improve the available systems. Further recommendations echoed in this letter to editor by Wiwanitkit, who outlined the research priorities on the development of appropriate combined disease monitoring systems and good policy to allocate available tools and technology in resource-limited settings for epidemic scenarios. The journal's editor, Professor Xiao-Nong Zhou, has therefore collated all parts of these discussions between authors in this letter to editor paper, in order to further promote research on a combined active and passive system to combat the present extending Ebola outbreak.

International Health

Volume 7 Issue 1 January 2015 http://inthealth.oxfordjournals.org/content/7/1.toc EDITORIAL

Chikungunya: here today, where tomorrow?

Stephen Higgs and Dana L. Vanlandingham

Until 2005, chikungunya virus (CHIKV) was a relatively little-studied pathogen restricted to parts of Africa and Asia. Epidemics were sporadic and separated by years of quiescence. In late 2004, the East Central South African genotype of CHIKV moved from Kenya onto the Indian Ocean island of Comoros. The global onslaught of CHIKV had begun. In November of 2005, viral isolates were identified with, what might normally be regarded as an insignificant, single alanine to valine mutation at position 226 of the envelope E1 gene.1 This simple mutation had a remarkable effect; making the virus approximately 100 times more infectious to the Asian tiger mosquito, Aedes albopictus, and it was this species that was transmitting the virus rather than the usual vector, Aedes aegypti.2 Subsequent 'second-step' mutations further enhanced the ability of the virus to infect and/or disseminate from the midgut to the salivary glands in Ae. albopictus. 3 However, these viruses can still be transmitted by Ae. aegypti. Within a year of the Indian Ocean lineage emerging, over 250 000 people had been infected. An epidemic in Asia began within months and has infected several million people in India and other Asian countries. Chikungunya infections occurred in many countries as a result of people travelling from areas with active transmission. The presence of tiger mosquito vector has been critical to enable localized CHIKV outbreaks in Italy and France. This species continues to invade new territory... **Human rabies deaths in Africa: breaking the cycle of indifference**

<u>Betty Dodeta,*</u>, <u>Mathurin C. Tejiokemb</u>, <u>Abdou-Rahman Aguemonc</u> and <u>Hervé Bourhyd</u> Author Affiliations

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dInstitut Pasteur, Unité Dynamique des lyssavirus et adaptation à l'hôte, WHO Collaborating Centre for Reference and Research on Rabies, Paris, France

Received July 22, 2014.

Revision received September 3, 2014.

Accepted September 3, 2014.

Abstract

The current outbreak of Ebola virus disease has mobilized the international community against this deadly disease. However, rabies, another deadly disease, is greatly affecting the African continent, with an estimated 25 000 deaths every year. And yet, the disease can be prevented by a vaccine, if necessary with immunoglobulin, even when administered after exposure to the rabies virus. Rabies victims die because of neglect and ignorance, because they are not aware of these life-saving biologicals, or because they cannot access them or do not have the money to pay for them. Breaking the cycle of indifference of rabies deaths in humans in Africa should be a priority of governments, international organizations and all stakeholders involved thigh coverage of vitamin A supplementation and measles vaccination during an

<u>High coverage of vitamin A supplementation and measles vaccination during an integrated Maternal and Child Health Week in Sierra Leone</u>

<u>Fatmata F. Sesaya,*</u>, <u>Mary H. Hodgesa</u>, <u>Habib I. Kamaraa</u>, <u>Mohamed Turaya</u>, <u>Adam Wolfeb</u>, <u>Thomas T. Sambac</u>, <u>Aminata S. Koromad</u>, <u>Wogba Kamarae</u>, <u>Amadou Fallf</u>, <u>Pamela Mitulaf</u>, <u>Ishata Contehf</u>, <u>Nuhu Makshag</u> and <u>Amara Jambaih</u>

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eNational HIV/AIDS Secretariat, Ministry of Health and Sanitation, Kingharman Road Freetown, Sierra Leone

fWorld Health Organization, Country Office, Sierra Leone and Inter Country Support Team for West Africa (IST-WA)

gUnited Nations Children's Fund, Country Office, Sierra Leone

hDirectorate of Disease Prevention and Control, Ministry of Health and Sanitation, Freetown, Sierra Leone

Abstract

Background

In May 2012, the twice-yearly Maternal and Child Health Week (MCHW) integrated vitamin A supplementation (VAS) and supplementary measles vaccination to reach all children 6–59 months in Sierra Leone. Following the MCHW, a post event coverage survey was conducted to validate VAS coverage and assess adverse events following immunization.

Methods

Using the WHO Expanded Program on Immunization sampling methodology, 30 clusters were randomly selected using population proportionate to size sampling. Fourteen caregivers of children 6–59 months were interviewed per cluster for precision of $\pm 5\%$. Responses were collected via mobile phones using EpiSurveyor.

Results

Overall VAS and measles coverage was 91.9% and 91.6%, respectively, with no significant differences by age group, sex, religion or occupation. Major reasons given for not receiving VAS and measles vaccination were not knowing about the MCHW or being out of the area. Significantly more mild adverse events (fever, pain at injection site) were reported via the post event coverage survey (29.1%) than MCHW (0.01%) (p<0.0001). Conclusion

The MCHW reached >90% of children in Sierra Leone with equitable coverage. Increased reporting of mild adverse events during the survey may be attributed to delayed onset after measles vaccination and/or direct inquiry from enumerators. Even mild adverse events following immunization requires strengthened reporting during and after vaccination campaigns.

International Journal of Epidemiology

Volume 43 Issue 6 December 2014 http://ije.oxfordjournals.org/content/current [Reviewed earlier]

International Journal of Infectious Diseases

January 2015 Volume 30, p1 http://www.ijidonline.com/current [Reviewed earlier]

JAMA

January 6, 2015, Vol 313, No. 1 http://jama.jamanetwork.com/issue.aspx

Viewpoint | January 6, 2015

<u>The President's National Security Agenda - Curtailing Ebola, Safeguarding the Future</u>

FREE

Lawrence O. Gostin, JD1; Henry A. Waxman, JD2; William Foege, MD, MPH3 [+] Author Affiliations

JAMA. 2015;313(1):27-28. doi:10.1001/jama.2014.16572. [Excerpt]

The Ebola epidemic is projected to affect tens of thousands in Sierra Leone, Liberia, and Guinea, with immense economic and social costs. Even in the United States, where only 1 patient with Ebola virus disease has died, the disease has spurred public fear, tested the readiness of the public health system, and led to measures such as enhanced border screening and state quarantines. The lesson of Ebola is clear: strong, resilient health systems are needed in Africa to curtail the outbreak at its source and in the United States to ameliorate risks and reassure the public.

The United States has led the global response to Ebola, devoting significant financial and human resources, deploying military troops, and sponsoring a groundbreaking United Nations Security Council resolution. Although there is some evidence that the spread of the disease is slowing in Liberia, the response of the United States is still not complete. Health systems in West Africa have been overwhelmed, and the US domestic public health system was not initially prepared, with inadequate training of and protection for health workers and inconsistent exercise of public health powers. This should not be a surprise given the severe budget cuts of recent years, including a 10% reduction in the Centers for Disease Control and Prevention's 2013 budget 1 and the loss of more than 50 000 state public health professionals. 2

President Obama is trying to address these challenges. On November 5, 2014, he submitted a \$6.2 billion emergency supplemental funding request to Congress to improve domestic and global health capacities in 3 critical areas: a surge of resources for containment and treatment in West Africa; enhanced prevention and detection of, and response to, Ebola entering the United States; and, perhaps most important, buttressing health systems to respond rapidly and flexibly to all hazards in the future. It is urgent that Congress support his request...

Original Investigation | January 6, 2015

<u>Quadrivalent HPV Vaccination and Risk of Multiple Sclerosis and Other</u> <u>Demyelinating Diseases of the Central Nervous System</u>

Nikolai Madrid Scheller, MB1; Henrik Svanström, MSc1; Björn Pasternak, MD, PhD1; Lisen Arnheim-Dahlström, PhD2; Karin Sundström, MD, PhD3; Katharina Fink, MD, DrMed4,5; Anders Hviid, DrMedSci1

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JAMA. 2015;313(1):54-61. doi:10.1001/jama.2014.16946.

Abstract

Importance

Case reports have suggested a link between human papillomavirus (HPV) vaccination and development of multiple sclerosis and other demyelinating diseases.

Objective

To investigate if quadrivalent HPV (qHPV) vaccination is associated with an increased risk of multiple sclerosis and other demyelinating diseases.

Design, Setting, and Participants

Using nationwide registers we identified a cohort of all females aged 10 years to 44 years in Denmark and Sweden, followed up from 2006 to 2013, information on gHPV vaccination, and data on incident diagnoses of multiple sclerosis and other demyelinating diseases. The primary analysis used a cohort design including vaccinated and unvaccinated study participants. A secondary analysis used a self-controlled case-series design including only cases. Both analyses used a 2-year risk period following vaccination.

Exposures

Information on qHPV vaccination was obtained through the national vaccination and prescription registers.

Main Outcomes and Measures

The primary outcomes were multiple sclerosis and a composite end point of other demyelinating diseases. Incidence rate ratios were estimated using Poisson regression, comparing rates of events in the 2-year risk periods following vaccination and in unvaccinated time periods. Results

The study included 3 983 824 females, among whom 789 082 received a total of 1 927 581 gHPV vaccine doses. During follow-up, 4322 multiple sclerosis cases and 3300 cases of other demyelinating diseases were identified, of which 73 and 90, respectively, occurred within the risk period. In the cohort analysis, there was no increased risk of multiple sclerosis (crude incidence rates, 6.12 events/100 000 person-years [95% CI, 4.86-7.69] and 21.54 events/100 000 person-years [95% CI, 20.90-22.20] for the vaccinated and unvaccinated periods; adjusted rate ratio, 0.90 [95% CI, 0.70-1.15]) or other demyelinating diseases (crude incidence rates, 7.54 events/100 000 person-years [95% CI, 6.13-9.27] and 16.14 events/100 000 person-years [95% CI, 15.58-16.71]; adjusted rate ratio, 1.00 [95% CI, 0.80-1.26]) associated with gHPV vaccination. Similarly, no increased risk was found using the selfcontrolled case-series design (multiple sclerosis: incidence ratio, 1.05 [95% CI, 0.79-1.38]; other demyelinating diseases: incidence ratio, 1.14 [95% CI, 0.88-1.47]).

Conclusions and Relevance

In this study with nationwide coverage of 2 Scandinavian countries, gHPV vaccination was not associated with the development of multiple sclerosis or other demyelinating diseases. These findings do not support concerns about a causal relationship between gHPV vaccination and demyelinating diseases.

JAMA Pediatrics

January 2015, Vol 169, No. 1 http://archpedi.jamanetwork.com/issue.aspx Viewpoint | January 2015

Advancing Children's Rights and Ensuring the Well-being of Children

Jonathan Todres, JD1 [+] Author Affiliations

JAMA Pediatr. 2015;169(1):5-6. doi:10.1001/jamapediatrics.2014.2470.

[Excerpt]

On November 20, 2014, the global community will celebrate the 25th anniversary of the United Nations Convention on the Rights of the Child, the most comprehensive international legal instrument on children's rights. The Convention is the most widely ratified human rights treaty in history, ratified by 194 countries. Only the United States, Somalia, and South Sudan have not ratified it. The United States signed the Convention in 1995 but, almost 20 years later, the United States has taken no further action (a treaty becomes legally binding only following

ratification). Yet, numerous US children continue to experience various harms. Because physicians witness many children's rights issues, pediatricians are well-positioned to inform policymakers on challenges children confront and the value of ensuring the rights of all children...

Journal of Community Health

Volume 39, Issue 6, December 2014 http://link.springer.com/journal/10900/39/6/page/1 [Reviewed earlier]

Journal of Epidemiology & Community Health

January 2015, Volume 69, Issue 1 http://jech.bmj.com/content/current [Reviewed earlier]

Journal of Global Ethics

<u>Volume 10</u>, Issue 3, 2014 <u>http://www.tandfonline.com/toc/rjge20/.U2V-Elf4L0I#.VAJEj2N4WF8</u> <u>Tenth Anniversary Forum: The Future of Global Ethics</u> [Reviewed earlier]

Journal of Global Infectious Diseases (JGID)

October-December 2014 Volume 6 | Issue 4 Page Nos. 139-198 http://www.jgid.org/currentissue.asp?sabs=n [Reviewed earlier]

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

Volume 25, Number 4, November 2014
http://muse.jhu.edu/journals/journal_of_health_care_for_the_poor_and_underserved/toc/hpu.25.4.html
[Reviewed earlier]

Journal of Health Organization and Management

<u>Issue 6 – December 2014</u> <u>http://link.springer.com/journal/10903/16/6/page/1</u> <u>Special Focus: Mental Health and Wellness</u> [Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 16, Issue 6, December 2014 http://link.springer.com/journal/10903/16/6/page/1 Special Issue Focus: Mental Health and Wellness

Journal of Immigrant & Refugee Studies

Volume 12, Issue 4, 2014

http://www.tandfonline.com/toc/wimm20/current#.VFWeF8I4WF9
Special Issue: New Forms of Intolerance in European Political Life
[Reviewed earlier]

Journal of Infectious Diseases

Volume 211 Issue 3 February 1, 2015 http://jid.oxfordjournals.org/content/current EDITORIAL COMMENTARY

Delayed BCG Vaccination—Time to Take a Shot

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3Stanford Immunology, Stanford University School of Medicine, California (See the major article by Toukam Tchakoute et al on pages 338–46.) [Excerpt]

The BCG vaccine is often derided for the lack of efficacy in preventing Mycobacterium tuberculosis infection and pulmonary disease in adults. However, BCG vaccine remains a highly effective and cost-efficient intervention to prevent tuberculous meningitis and miliary tuberculosis in infants, reducing the incidence of these life-threatening and debilitating infections by approximately 75% [1, 2]. In addition, BCG vaccine coverage rates typically exceed those of other vaccines because it can be administered at birth as a single vaccination [3].

However, this strength of the BCG vaccination strategy has become a liability because of the risks of administering BCG vaccine to human immunodeficiency virus (HIV)–infected infants. The HIV diagnosis is typically not made until the second or third month of life in resource-limited settings, and BCG vaccination in this population results in unacceptably high rates of disseminated BCG disease of 417–992 cases per 100,000 vaccinations, with a mortality of approximately 75% [4–6]. To put this in perspective, this rate of disseminated BCG disease exceeds the rate of disseminated disease due to M. tuberculosis in the same South African population of HIV-infected infants, which is estimated to be 241 cases per 100,000 [7]. In light of this significant risk for the vaccine to cause harm, the World Health Organization (WHO) now identifies known HIV infection in infants, or HIV exposure and symptoms concerning for HIV, as contraindications to BCG vaccination [8, 9]. The rationale for this recommendation is augmented by the unknown clinical efficacy of BCG vaccination in HIV-infected infants and the immunologic data suggesting that BCG given at birth is unlikely to be efficacious in this population [10]....

<u>Delaying BCG Vaccination Until 8 Weeks of Age Results in Robust BCG-Specific T-Cell Responses in HIV-Exposed Infants</u>

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Presented in part: 6th South African AIDS Conference, Durban, South Africa, June 2013; World Society for Pediatric Infectious Diseases Conference, Cape Town, South Africa, November 2013. *Abstract*

Background

BCG vaccination prevents disseminated tuberculosis in children, but it is contraindicated for persons with human immunodeficiency virus (HIV) infection because it can result in severe disease in this population. In tuberculosis-endemic regions, BCG vaccine is administered soon after birth, before in utero and peripartum HIV infection is excluded. We therefore assessed the immunogenicity of BCG vaccine in HIV-exposed infants who received BCG at birth or at 8 weeks of age.

Methods

HIV-exposed, uninfected infants were randomly assigned to receive BCG vaccination at birth (the early vaccination arm) or 8 weeks of age (the delayed vaccination arm). BCG-specific proliferative and intracellular cytokine responses were assessed in 28 infants per arm at 6, 8, and 14 weeks of life.

Results

There was no difference in BCG-specific T-cell proliferation between the study arms 6 weeks after vaccination. However, at 14 weeks of age, the frequency of interferon γ -expressing CD4+ T cells and multifunctional BCG-specific responses in the delayed vaccinated arm were significantly higher than those in the early vaccination arm (P = .021 and P = .011, respectively).

Conclusions

The immunogenicity of BCG vaccination in HIV-exposed, uninfected infants is not compromised when delayed until 8 weeks of age and results in robust BCG-specific T-cell responses at 14 weeks of age. These findings support further evaluation of this modified BCG vaccination strategy for HIV-exposed infants.

Clinical Trials Registration. NCT02062580.

Live Attenuated and Inactivated Influenza Vaccines in Children

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Presented in part: American Society for Virology, 31st Annual Meeting, Madison, Wisconsin 21–25 July 2012; Pediatric Academic Societies, Boston, Massachuetts, 28 April–1 May, 2012. a Present affiliation: Food and Drug Administration Center for Drug Evaluation and Research, Bethesda, Maryland.

b A. G. H. and A. M. K. contributed equally to this work.

Abstract

Background

Live attenuated influenza vaccine (LAIV) and inactivated influenza vaccine (IIV) are available for children. Local and systemic immunity induced by LAIV followed a month later by LAIV and IIV followed by LAIV were investigated with virus recovery after LAIV doses as surrogates for protection against influenza on natural exposure.

Methods.

Fifteen children received IIV followed by LAIV, 13 an initial dose of LAIV, and 11 a second dose of LAIV. The studies were done during autumn 2009 and autumn 2010 with the same seasonal vaccine (A/California/07/09 [H1N1], A/Perth/16/09 [H3N2], B/Brisbane/60/08). Results.

Twenty-eight of 39 possible influenza viral strains were recovered after the initial dose of LAIV. When LAIV followed IIV, 21 of 45 viral strains were identified. When compared to primary LAIV infection, the decreased frequency of shedding with the IIV-LAIV schedule was significant (P = .023). With LAIV-LAIV, the fewest viral strains were recovered (3/33)—numbers significantly lower (P < .001) than shedding after initial LAIV and after IIV-LAIV (P < .001). Serum hemagglutination inhibition antibody responses were more frequent after IIV than LAIV (P = .02). In contrast, more mucosal immunoglobulin A responses were seen with LAIV. Conclusions.

LAIV priming induces greater inhibition of virus recovery on LAIV challenge than IIV priming. The correlate(s) of protection are the subject of ongoing analysis. Clinical Trials Registration. NCT01246999.

The Journal of Law, Medicine & Ethics

Winter 2014 Volume 42, Issue 4 Pages 408–602

http://onlinelibrary.wiley.com/doi/10.1111/jlme.2014.42.issue-4/issuetoc

Special Issue: SYMPOSIUM: The Buying and Selling of Health Care

Global Emergency Legal Responses to the 2014 Ebola Outbreak: Public Health and the Law (pages 595–601)

James G. Hodge Jr., Leila Barraza, Gregory Measer and Asha Agrawal Article first published online: 6 JAN 2015 | DOI: 10.1111/jlme.12179 [No abstract]

Journal of Medical Ethics

January 2015, Volume 41, Issue 1 http://jme.bmj.com/content/current JME40: Good medical ethics

Paper

The impossibility of informed consent?

Kenneth Boyd

Received 1 September 2014 Revised 26 September 2014 Accepted 23 October 2014 Abstract

The problematic nature of informed consent to medical treatment and research, and its relation to autonomy, trust and clinical practice, has been addressed on many occasions and from a variety of ethical perspectives in the pages of the Journal of Medical Ethics. This paper gives an account of how discussion of these issues has developed and changed, by describing a number of significant contributions to these debates which provide examples of 'doing good medical ethics' over the 40 years of the Journal's publication.

Journal of Medical Internet Research

Vol 16, No 12 (2014): December http://www.jmir.org/2014/12 [Reviewed earlier]

Journal of Medical Microbiology

December 2014; 63 (Pt 12) http://jmm.sgmjournals.org/content/current [Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)

Volume 3 Issue 4 December 2014 http://jpids.oxfordjournals.org/content/current [Reviewed earlier]

Journal of Pediatrics

Volume 165, Issue 6, p1073-1280 December 2014 http://www.jpeds.com/current [Reviewed earlier]

Journal of Public Health Policy

Volume 36, Issue 1 (February 2015) http://www.palgrave-journals.com/jphp/journal/v36/n1/index.html Editorial

Lessons from the public health response to Ebola

Journal of Public Health Policy (2015) 36, 1–3. doi:10.1057/jphp.2014.51; published online 11 December 2014

Anthony Robbins Co-Editor and Ruth Berkelman Member, JPHP Editorial Board

Anything we say today about Ebola is likely to seem dated by the time it is posted online in weeks or appears in print in months. So we look back, to consider missed opportunities, and into the unknown future to avoid worldwide 'surprise' again.

How could the public health world have been so ill prepared for this year's Ebola virus disease outbreaks in Guinea, Sierra Leone, and Liberia? Although these outbreaks have grabbed the whole world's attention, we can only describe the response as 'scrambling to catch-up'.

The hemorrhagic fever caused by the Ebola virus was first described in 1976 in what was then Zaire. There have been additional small outbreaks in sub-Saharan Africa. Uganda and other countries controlled outbreaks, but not without resources and an organized response.

It looks like not everyone was asleep. Lab researchers did what they are good at, and the molecular biology of the Ebola virus is rather well described and advanced in understanding. Promising candidate vaccines and antiviral therapies have been developed but they have not progressed to licensure. Was testing and licensure left largely to an industry that saw no profit selling an Ebola vaccine to the world's poorest countries?

Research in the field has been less robust than in the laboratory. Months into the epidemic, there still seemed to be confusion about how the virus was spread. The question of whether some people are more likely to spread the disease than others, so-called 'super-spreaders', has lingered. More applied research is surely needed. We learned recently that management of waste disposal – from bodily fluids to personal protective equipment and mattresses – remains inadequately studied. Does everything need to be buried or burned? What works efficiently?

Perhaps it is unfair to expect the world's major research institutes – the Institut Pasteur, the Karolinska, or the US National Institutes of Health – to put more researchers in the field. But, is there an explanation for the World Health Organization's (WHO) failure to organize assistance for countries with inadequate resources; to help them prepare for Ebola and other infectious disorders? In the case of Ebola, WHO knew that with preparation and resources, the disease had, in the past, been successfully contained. New global interest in noncommunicable diseases4 must not absolve public health officials for their failure to prepare for infectious disease outbreaks.

Médecins Sans Frontières (MSF) has sent doctors and nurses into the field to help where resources are scarce. They also conduct field research. MSF's applied research, organized by Epicentre MSF in Paris. Epicentre studies field operations of MSF to learn what works and what does not. They learn what knowledge, strategies, and resources are needed, and how to provide care and protection. MSF developed guidance for the use of personal protective equipment.

In June 2014 MSF was outspoken, calling for a robust response and stating that the outbreak was 'out of control' and that they had reached their limit in being able to care for patients with Ebola virus disease in 60 locations across Liberia, Guinea, and Sierra Leone. Was anyone listening? It took 6 weeks until WHO deemed Ebola a 'Public Health Emergency of International Concern' and called for a coordinated international response. Countries facing occasional imported cases were in a panic about how to respond at home, while thousands of people in West Africa became infected with Ebola.

Our list of 'pending' infectious challenges is far from exhaustive, but it confirms that there are many threats out there. Influenza has received some attention. The coronaviruses – Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome – and the paramyxoviruses – Nipah virus – remain serious threats to health globally. 5, 6 Current efforts to control multi-drug resistant tuberculosis are dangerously 'out of step' with this grave peril. 7, 8 Mosquito control needs to be reinforced so that Chikungunya and Dengue can be prevented. We must look ahead at the full range of threats.

Can we learn from Ebola? We must make sure that lab research, plus applied research and field studies, and the resources for care and prevention will be developed now so that we will not be 'surprised' in the future as we seem to have been with Ebola.

[References]

Editorial

Commentary: Ebola: The haves and the have-nots

Adolfo Martínez Palomoa

aCenter for Advanced Studies, Molecular Pathogenesis, Avenida IPN 2508, Mexico City (D.F.) Journal of Public Health Policy (2015) 36, 4–6. doi:10.1057/jphp.2014.50; published online 27 November 2014

Abstract

The Ebola epidemic exemplifies the importance of social determinants of health: poverty and illiteracy, among others.

<u>Viewpoint: The role of sanitation in malnutrition – A science and policy controversy</u> in India

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Abstract

Over the past decade, India's economic growth has been remarkable – yet almost half of India's children under 5 remain stunted. The National Food Security Bill is the country's response to this critical situation. Studies reveal that Indian children are chronically undernourished, not only because of lack of food but also because of recurring gastrointestinal infections. The stunting problem revolves more around lack of sanitation than food insecurity. Despite acknowledging that malnutrition is 'complex and multidimensional', government action has consisted largely of nutritional interventions and subsidized food. Although improvements in sanitation would be the most effective way to reduce excessively high levels of chronic undernutrition and stunting, a review of policy formulation and implementation reveals deficits and disconnects with available scientific evidence. It is time to change these mistaken assumptions and focus on improving access and use of safe sanitation facilities to achieve India's nutritional goals.

Journal of the Royal Society – Interface

06 February 2015; volume 12, issue 103 http://rsif.royalsocietypublishing.org/content/current [New issue; No relevant content]

Journal of Virology

<u>December 2014, volume 88, issue 24</u> <u>http://jvi.asm.org/content/current</u> [Reviewed earlier]

The Lancet

Jan 10, 2015 Volume 385 Number 9963 p89-200 e4 http://www.thelancet.com/journals/lancet/issue/current Comment

Beyond Ebola: a new agenda for resilient health systems

Marie Paule Kieny, Delanyo Dovlo

DOI: http://dx.doi.org/10.1016/S0140-6736(14)62479-X Summary

A resilient health system is one able to absorb the shock of an emergency like Ebola and at the same time continue to provide regular health services, leaving other sectors of the country fully functioning. In Guinea, Liberia, and Sierra Leone, the 2014 Ebola outbreak has claimed many lives and laid waste to economies, food provision, and development. The World Bank's forecast1 of tens of billions of dollars lost for the three affected countries and the broader west Africa region points to the interdependence between health and countries' wider socioeconomic landscape.

Comment

Offline: Solving WHO's "persisting weaknesses" (part 1)

Richard Horton

DOI: http://dx.doi.org/10.1016/S0140-6736(14)62485-5

When the 34 members of WHO's Executive Board gather in Geneva on Jan 25—first, for a special session on the response to the Ebola outbreak and, second, for its 136th meeting—countries will have an unprecedented opportunity to reflect on the future of the world's only global health agency. Why unprecedented? Because, in WHO's own words (from documents submitted to the Board and available on WHO's website), Ebola has put "enormous strain" on the agency's managerial structures and systems. The outbreak has had a "significant impact" on WHO's non-Ebola work, with the result that "time-bound projects will be affected". *Articles*

Global, regional, and national age—sex specific all-cause and cause-specific mortality for 240 causes of death, 1990—2013: a systematic analysis for the Global Burden of Disease Study 2013

GBD 2013 Mortality and Causes of Death Collaborators

Collaborators listed at the end of the Article

Published Online: 17 December 2014

DOI: http://dx.doi.org/10.1016/S0140-6736(14)61682-2

Summary Background

Up-to-date evidence on levels and trends for age-sex-specific all-cause and cause-specific mortality is essential for the formation of global, regional, and national health policies. In the Global Burden of Disease Study 2013 (GBD 2013) we estimated yearly deaths for 188 countries between 1990, and 2013. We used the results to assess whether there is epidemiological convergence across countries.

Methods

We estimated age-sex-specific all-cause mortality using the GBD 2010 methods with some refinements to improve accuracy applied to an updated database of vital registration, survey, and census data. We generally estimated cause of death as in the GBD 2010. Key improvements included the addition of more recent vital registration data for 72 countries, an updated verbal autopsy literature review, two new and detailed data systems for China, and more detail for Mexico, UK, Turkey, and Russia. We improved statistical models for garbage code redistribution. We used six different modelling strategies across the 240 causes; cause of death ensemble modelling (CODEm) was the dominant strategy for causes with sufficient information. Trends for Alzheimer's disease and other dementias were informed by metaregression of prevalence studies. For pathogen-specific causes of diarrhoea and lower respiratory infections we used a counterfactual approach. We computed two measures of convergence (inequality) across countries: the average relative difference across all pairs of

countries (Gini coefficient) and the average absolute difference across countries. To summarise broad findings, we used multiple decrement life-tables to decompose probabilities of death from birth to exact age 15 years, from exact age 15 years to exact age 50 years, and from exact age 50 years to exact age 75 years, and life expectancy at birth into major causes. For all quantities reported, we computed 95% uncertainty intervals (UIs). We constrained cause-specific fractions within each age-sex-country-year group to sum to all-cause mortality based on draws from the uncertainty distributions.

Findings

Global life expectancy for both sexes increased from 65.3 years (UI 65.0–65.6) in 1990, to 71.5 years (UI 71·0-71·9) in 2013, while the number of deaths increased from 47·5 million (UI 46·8–48·2) to 54·9 million (UI 53·6–56·3) over the same interval. Global progress masked variation by age and sex: for children, average absolute differences between countries decreased but relative differences increased. For women aged 25–39 years and older than 75 years and for men aged 20-49 years and 65 years and older, both absolute and relative differences increased. Decomposition of global and regional life expectancy showed the prominent role of reductions in age-standardised death rates for cardiovascular diseases and cancers in high-income regions, and reductions in child deaths from diarrhoea, lower respiratory infections, and neonatal causes in low-income regions. HIV/AIDS reduced life expectancy in southern sub-Saharan Africa. For most communicable causes of death both numbers of deaths and age-standardised death rates fell whereas for most non-communicable causes. demographic shifts have increased numbers of deaths but decreased age-standardised death rates. Global deaths from injury increased by 10.7%, from 4.3 million deaths in 1990 to 4.8 million in 2013; but age-standardised rates declined over the same period by 21%. For some causes of more than 100 000 deaths per year in 2013, age-standardised death rates increased between 1990 and 2013, including HIV/AIDS, pancreatic cancer, atrial fibrillation and flutter, drug use disorders, diabetes, chronic kidney disease, and sickle-cell anaemias. Diarrhoeal diseases, lower respiratory infections, neonatal causes, and malaria are still in the top five causes of death in children younger than 5 years. The most important pathogens are rotavirus for diarrhoea and pneumococcus for lower respiratory infections. Country-specific probabilities of death over three phases of life were substantially varied between and within regions. Interpretation

For most countries, the general pattern of reductions in age-sex specific mortality has been associated with a progressive shift towards a larger share of the remaining deaths caused by non-communicable disease and injuries. Assessing epidemiological convergence across countries depends on whether an absolute or relative measure of inequality is used. Nevertheless, age-standardised death rates for seven substantial causes are increasing, suggesting the potential for reversals in some countries. Important gaps exist in the empirical data for cause of death estimates for some countries; for example, no national data for India are available for the past decade.

Funding

Bill & Melinda Gates Foundation.

The Lancet Global Health

Jan 2015 Volume 3 Number 1 e1-e61 http://www.thelancet.com/journals/langlo/issue/current [Reviewed earlier]

The Lancet Infectious Diseases

Jan 2015 Volume 15 Number 1 p1-130 http://www.thelancet.com/journals/laninf/issue/current [Reviewed earlier]

Maternal and Child Health Journal

Volume 19, Issue 1, January 2015 http://link.springer.com/journal/10995/19/1/page/1 [New issue; No relevant content]

Medical Decision Making (MDM)

January 2015; 35 (1) http://mdm.sagepub.com/content/current [Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy
December 2014 Volume 92, Issue 4 Pages 633–840
http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1468-0009/currentissue
[Reviewed earlier]

Nature

Volume 517 Number 7533 pp121-236 8 January 2015 http://www.nature.com/nature/current_issue.html [New issue; No relevant content]

Nature Medicine

January 2015, Volume 21 No 1 pp1-98 http://www.nature.com/nm/journal/v21/n1/index.html [New issue; No relevant content]

Nature Reviews Immunology

January 2015 Vol 15 No 1 http://www.nature.com/nri/journal/v15/n1/index.html [New issue; No relevant content]

New England Journal of Medicine

January 8, 2015 Vol. 372 No. 2 http://www.nejm.org/toc/nejm/medical-journal Original Article

Efficacy of a Tetravalent Dengue Vaccine in Children in Latin America

Luis Villar, M.D., Gustavo Horacio Dayan, M.D., José Luis Arredondo-García, M.D., Doris Maribel Rivera, M.D., Rivaldo Cunha, M.D., Carmen Deseda, M.D., Humberto Reynales, M.D., Maria Selma Costa, M.D., Javier Osvaldo Morales-Ramírez, M.D., Gabriel Carrasquilla, M.D., Luis Carlos Rey, M.D., Reynaldo Dietze, M.D., Kleber Luz, M.D., Enrique Rivas, M.D., Maria Consuelo Miranda Montoya, M.D., Margarita Cortés Supelano, M.D., Betzana Zambrano, M.D., Edith Langevin, M.Sc., Mark Boaz, Ph.D., Nadia Tornieporth, M.D., Melanie Saville, M.B., B.S., and Fernando Noriega, M.D. for the CYD15 Study Group

N Engl J Med 2015; 372:113-123 <u>January 8, 2015</u> DOI: 10.1056/NEJMoa1411037 Abstract

Background

In light of the increasing rate of dengue infections throughout the world despite vector-control measures, several dengue vaccine candidates are in development.

Methods

In a phase 3 efficacy trial of a tetravalent dengue vaccine in five Latin American countries where dengue is endemic, we randomly assigned healthy children between the ages of 9 and 16 years in a 2:1 ratio to receive three injections of recombinant, live, attenuated, tetravalent dengue vaccine (CYD-TDV) or placebo at months 0, 6, and 12 under blinded conditions. The children were then followed for 25 months. The primary outcome was vaccine efficacy against symptomatic, virologically confirmed dengue (VCD), regardless of disease severity or serotype, occurring more than 28 days after the third injection. Results

A total of 20,869 healthy children received either vaccine or placebo. At baseline, 79.4% of an immunogenicity subgroup of 1944 children had seropositive status for one or more dengue serotypes. In the per-protocol population, there were 176 VCD cases (with 11,793 person-years at risk) in the vaccine group and 221 VCD cases (with 5809 person-years at risk) in the control group, for a vaccine efficacy of 60.8% (95% confidence interval [CI], 52.0 to 68.0). In the intention-to-treat population (those who received at least one injection), vaccine efficacy was 64.7% (95% CI, 58.7 to 69.8). Serotype-specific vaccine efficacy was 50.3% for serotype 1, 42.3% for serotype 2, 74.0% for serotype 3, and 77.7% for serotype 4. Among the severe VCD cases, 1 of 12 was in the vaccine group, for an intention-to-treat vaccine efficacy of 95.5%. Vaccine efficacy against hospitalization for dengue was 80.3%. The safety profile for the CYD-TDV vaccine was similar to that for placebo, with no marked difference in rates of adverse events.

Conclusions

The CYD-TDV dengue vaccine was efficacious against VCD and severe VCD and led to fewer hospitalizations for VCD in five Latin American countries where dengue is endemic. (Funded by Sanofi Pasteur; ClinicalTrials.gov number, NCT01374516.)

Editorial

<u>Preventing Dengue — Is the Possibility Now a Reality?</u>

Stephen J. Thomas, M.D.

N Engl J Med 2015; 372:172-173 <u>January 8, 2015</u> DOI: 10.1056/NEJMe1413146

Dengue is a mosquito-borne flaviviral illness that is endemic in the tropics and subtropics. An estimated 390 million infections occur annually, of which 96 million have clinical manifestations. 1 Although mortality is relatively lower than that for other tropical infectious diseases, the scale of human suffering and economic resources that are expended to control dengue makes it a major global public health problem. 2 The factors driving transmission and infection persist without evidence of decline. For these reasons, the world needs a safe and effective dengue vaccine.

Infection with one of the four types of dengue virus (serotypes 1, 2, 3, and 4) may result in an asymptomatic infection, a mild nonspecific viral illness, classic dengue fever, or severe dengue manifested by plasma leakage, hemorrhagic tendencies, and possibly death. Patients with a second infection with a different serotype are at increased risk for severe disease. The mechanisms responsible for enhanced disease have not been completely elucidated. It is theorized the humoral and cellular convalescent immune profiles that are present after a first infection may not only fail to control a second infection with a different serotype but may also facilitate increased target-cell infection, viral replication, and generation of a so-called proinflammatory cytokine storm. 3,4

The dengue-vaccine field is facing numerous challenges. First, a viable dengue vaccine must be capable of protecting against disease caused by any of the four serotypes, a process that has been burdened by the absence of a validated animal model of disease or a well-characterized human infection model. The incomplete understanding of dengue immunopathology introduces risk into clinical development programs. Finally, the reliance on neutralizing antibody assays, which are notorious for interassay variability and cross-reactivity among serotypes, to generate immunologic end-point data introduces error into data interpretation.5

After decades of attempts to develop a dengue vaccine, the results of a phase 3 efficacy trial that are now described in the Journal are a milestone. The vaccine candidate that is described by Villar et al. 6 has been tested in three clinical end-point studies. In all the studies, three doses of vaccine or a control injection were administered at 0, 6, and 12 months, and all efficacy determinations were made at study month 25.

The first study was a phase 2b efficacy trial involving children between the ages of 4 and 11 years in a single center in Thailand. The trial did not meet the primary efficacy end point, with a per-protocol efficacy of 30.2%, and showed wide variation in serotype-specific efficacy: 55.6% for serotype 1, 9.2% for serotype 2, 75.3% for serotype 3, and 100% for serotype 4.7 The first phase 3 trial, which was conducted in five Asian countries and involved children between the ages of 2 and 14 years, showed a per-protocol efficacy of 56.5%, with a similar trend in serotype-specific efficacy: 50.0% for serotype 1, 35.0% for serotype 2, 78.4% for serotype 3, and 75.3% for serotype 4.8 The phase 3 trial by Villar et al., which was conducted in five Latin America countries and involved children between the ages of 9 and 16 years, had a per-protocol efficacy of 60.8%, with serotype-specific efficacies of 50.3%, 42.3%, 74.0%, and 77.7%, respectively. Additional end points included efficacy against hospitalization (80.3%) and against severe dengue (95.5%). In each of the three studies, the cohort was highly immune to at least one of the serotypes at baseline. In the phase 2b and 3 trials in Asia, average rates of seropositive status for one or more dengue serotypes were 69.5% and 67.5%, respectively; in the study by Villar et al., the average rate was 79.4%.

These studies have answered important questions with respect to the development of a dengue vaccine but have generated numerous others. Vaccine safety, immunogenicity, and efficacy were consistent across the phase 3 studies, with measures of performance similar to those in the phase 2b trial. There were no safety signals identified and no evidence of the hypothetical risk of administering a dengue vaccine to children with a mixture of seropositive and seronegative status who are living in an area in which dengue is endemic. However, it is not clear whether this favorable safety profile will be sustained through periods of waning immunity and successive dengue exposures remote from vaccination.

Vaccination of children with seropositive status produced high seroconversion rates and broad, potent neutralizing-antibody profiles. Despite such elicitation of antibody responses, why was there such disparity in efficacy across the dengue serotypes? Could too much preexisting

immunity interfere with a serotype-specific vaccine response, leaving deficits in tetravalent efficacy? It is possible that the antibodies that were measured after vaccination were not all neutralizing but were a mixture of neutralizing and cross-reactive antibodies that were poorly functioning and potentially enhancing. If so, this could explain the discordance between the favorable serotype-specific serologic response to vaccination and the absence of corresponding serotype-specific efficacy.

Efficacy was higher in vaccine recipients with seropositive status than in those with seronegative status. Does the inferior efficacy in seronegative vaccine recipients preclude the usefulness of this vaccine for travelers or military personnel? If the vaccine is licensed and an immunization program is implemented, will this factor have an effect on its age-specific placement in the vaccination schedule?

The observed reduction in the severity of clinical disease and the prevention of hospitalization are encouraging. Although outpatient dengue has a substantial societal cost, dengue requiring hospitalization reflects morbidity. 10 Is it possible that a vaccine candidate with a modest overall efficacy could be licensed and included in a national immunization program on the basis of its ability to reduce morbidity and other outcomes driving expenditures?

The efficacy trial by Villar et al. shows that we can protect populations from dengue disease and perhaps even reduce the proportion of patients with severe disease. Although the available results are not broadly generalizable across diverse populations, a foundation for additional studies has been laid. The global enrollment of more than 30,000 children in the phase 2b and 3 studies has assuaged fears focusing on the theoretical risk that dengue vaccination could predispose recipients to enhanced rates of severe disease. It remains to be seen whether licensure will be sought on the basis of these data and what effect this could have on future attempts to conduct efficacy trials with different candidate vaccines. For now, practitioners should remain optimistic that one day it will be possible to prevent dengue.

The Pediatric Infectious Disease Journal

December 2014 - Volume 33 - Issue 12 pp: 1211-1312,e316-e337 http://journals.lww.com/pidj/pages/currenttoc.aspx [Reviewed earlier]

Pediatrics

January 2015, VOLUME 135 / ISSUE 1 http://pediatrics.aappublications.org/current.shtml Article

Registry-Linked Electronic Influenza Vaccine Provider Reminders: A Cluster-Crossover Trial

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dBiomedical Informatics, and
eSociomedical Sciences, Columbia University, New York, New York; and

cNewYork—Presbyterian Hospital, New York, New York Abstract

OBJECTIVE: To determine the impact of a vaccination reminder in an electronic health record supplemented with data from an immunization information system (IIS).

METHODS: A noninterruptive influenza vaccination reminder, based on a real-time query of hospital and city IIS, was used at 4 urban, academically affiliated clinics serving a low-income population. Using a randomized cluster-crossover design, each study site had "on" and "off" period during the fall and winter of 2011–2012. Influenza vaccination during a clinic visit was assessed for 6-month to 17-year-old patients. To assess sustainability, the reminder was active at all sites during the 2012–2013 season.

RESULTS: In the 2011–2012 season, 8481 unique non-up-to-date children had visits. Slightly more non–up-to-date children seen when the reminder was 'on' were vaccinated than when 'off' (76.2% vs 73.8%; P = .027). Effects were seen in the winter (67.9% vs 62.2%; P = .005), not fall (76.8% vs 76.5%). The reminder also increased documentation of the reason for vaccine non-administration (68.1% vs 41.5%; P < .0001). During the 2011-2012 season, the reminder displayed for 8630 unique visits, and clinicians interacted with it in 83.1% of cases where patients required vaccination. During the 2012-2013 season, it displayed for 22 248 unique visits; clinicians interacted with it in 84.8% of cases.

CONCLUSIONS: An IIS-linked influenza vaccination reminder increased vaccination later in the winter when fewer vaccine doses are usually given. Although the reminder did not require clinicians to interact with it, they frequently did; utilization did not wane over time.

Pharmaceutics

<u>Volume 6</u>, Issue 4 (December 2014), Pages 543http://www.mdpi.com/1999-4923/6/4 [Reviewed earlier]

Pharmacoeconomics

Volume 33, Issue 1, January 2015 http://link.springer.com/journal/40273/33/1/page/1 [No relevant content]

PLoS Currents: Outbreaks

http://currents.plos.org/outbreaks/ (Accessed 10 January 2015) [No new relevant content]

PLoS Medicine

(Accessed 10 January 2015) http://www.plosmedicine.org/ Essav

Randomized Controlled Trials in Environmental Health Research: Unethical or Underutilized?

Ryan W. Allen mail, Prabjit K. Barn, Bruce P. Lanphear

Summary Points

- :: Efficacious environmental interventions are needed because environmental risks account for a large fraction of the global disease burden.
- :: Randomized controlled trials have not been widely embraced by environmental health researchers and comprise less than 1% of research publications in the field.
- :: Additional randomized controlled trials in environmental health would complement a strong tradition of observational research by creating new knowledge on exposure—health relationships, providing more definitive evidence of causality, identifying efficacious interventions to reduce or eliminate hazards, and countering the perception that environmental risks are evaluated with inadequate rigor.
- :: Ethical issues—including clinical equipoise, the distribution of benefits and risks, and the relevance of the intervention and health outcome to the study population—must be carefully considered before conducting a randomized controlled trial of an environmental intervention.

PLoS Neglected Tropical Diseases

http://www.plosntds.org/ (Accessed 10 January 2015)

Research Article

<u>Effectiveness of Routine BCG Vaccination on Buruli Ulcer Disease: A Case-Control Study in the Democratic Republic of Congo, Ghana and Togo</u>

Richard Odame Phillips, Delphin Mavinga Phanzu, Marcus Beissner, Kossi Badziklou, Elysée Kalundieko Luzolo, Fred Stephen Sarfo, Wemboo Afiwa Halatoko, Yaw Amoako, Michael Frimpong, Abass Mohammed Kabiru, Ebekalisai Piten, Issaka Maman, Bawimodom Bidjada, [...], Karl-Heinz Herbinger mail, [view all]

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Abstract Background

The only available vaccine that could be potentially beneficial against mycobacterial diseases contains live attenuated bovine tuberculosis bacillus (Mycobacterium bovis) also called Bacillus Calmette-Guérin (BCG). Even though the BCG vaccine is still widely used, results on its effectiveness in preventing mycobacterial diseases are partially contradictory, especially regarding Buruli Ulcer Disease (BUD). The aim of this case-control study is to evaluate the possible protective effect of BCG vaccination on BUD.

Methodology

The present study was performed in three different countries and sites where BUD is endemic: in the Democratic Republic of the Congo, Ghana, and Togo from 2010 through 2013. The large study population was comprised of 401 cases with laboratory confirmed BUD and 826 controls, mostly family members or neighbors.

Principal Findings

After stratification by the three countries, two sexes and four age groups, no significant correlation was found between the presence of BCG scar and BUD status of individuals. Multivariate analysis has shown that the independent variables country (p = 0.31), sex (p = 0.24), age (p = 0.96), and presence of a BCG scar (p = 0.07) did not significantly influence the development of BUD category I or category II/III. Furthermore, the status of BCG vaccination was also not significantly related to duration of BUD or time to healing of lesions. Conclusions

In our study, we did not observe significant evidence of a protective effect of routine BCG vaccination on the risk of developing either BUD or severe forms of BUD. Since accurate data on BCG strains used in these three countries were not available, no final conclusion can be drawn on the effectiveness of BCG strain in protecting against BUD. As has been suggested for tuberculosis and leprosy, well-designed prospective studies on different existing BCG vaccine strains are needed also for BUD.

Author Summary

After tuberculosis and leprosy, Buruli Ulcer Disease (BUD) is the third most common human mycobacterial disease. The only available vaccine that could be potentially beneficial against these diseases is BCG. Even though BCG vaccine is widely used, the results on its effectiveness are partially contradictory, probably since different BCG strains are used. The aim of this study was to evaluate the possible protective effect of BCG vaccines on BUD. The present study was performed in three different countries and sites where BUD is endemic: in the Democratic Republic of the Congo, Ghana, and Togo from 2010 through 2013. The large study population was comprised of 401 cases with laboratory confirmed BUD and 826 controls, mostly family members or neighbors. Considering the three countries, sex, and age, the analysis confirmed that the BCG vaccination did not significantly decrease the risk for developing BUD or for developing severe forms of BUD. Furthermore, the status of BCG vaccination was also not significantly related to duration of BUD or to time to healing of lesions. In our study, we could not find any evidence of a protective effect of routine BCG vaccination on BUD.

<u>Strengthening Research Capacity—TDR's Evolving Experience in Low- and Middle-Income Countries</u>

Olumide A. T. Ogundahunsi mail, Mahnaz Vahedi, Edward M. Kamau, Garry Aslanyan, Robert F. Terry, Fabio Zicker, Pascal Launois

Published: January 08, 2015

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Introduction

In the 1970s, very few international programmes provided support to strengthen tropical disease research capacity and most research for the diseases prevalent in low- and middle-income countries (LMICs) was done by scientists and institutions in advanced industrialised countries. Soon after inception in 1974, TDR established a research capacity strengthening (RCS) programme with a goal to train individuals and strengthen research capacity in disease-endemic countries so that they can find and implement appropriate solutions to their health problems [1], [2]. At that time, very little research addressed the burden of these diseases. For most of its existence, up to a third of TDR's total resources were earmarked for strengthening research capacity in LMICs. In the past 20 years, other charities, foundations, health research councils, and development agencies have begun their own capacity strengthening programmes, so today, the concept is well accepted, although the means to achieve the end vary [3]–[5]. This paper presents a broad description from the TDR secretariat's perspective on evolving approaches used to promote research capacity strengthening in LMICs. The paper is part of a special series commemorating TDR's 40-year anniversary.

TDR has an intertwined approach: training support for individuals and collaborative research programmes for institutions [1], [2]. Research training requires adequate research facilities, which may need strengthening. Similarly, strengthening an institution so that it can fully participate in a research partnership often calls for supporting training facilities and staff. The specific needs and priorities that are funded by TDR have been identified by a capacity building steering committee and approved by the TDR Scientific and Technical Advisory Committee

(STAC), which comprises 15 to 18 experts in a wide range of scientific disciplines who peer review the programme's scientific and technical activities.

TDR's placement within the United Nations system provides close collaboration with country offices of not only the World Health Organization but also of other co-sponsoring agencies UNICEF and UNDP, and with the World Bank. As a consequence, those who are supported by TDR often work closely with disease control programmes as well as other international organizations.

Regular reviews of TDR's research capacity strengthening programmes have helped reorient the strategy as needed, shifting focus from institutional strengthening in the 1980s to human resources strengthening in the 1990s [1], as well as identifying the need to move to a more demand-driven model of national health research systems [4]. Over the years, TDR has continued to support multidisciplinary research, particularly to bring social science research and biomedical research together through different mechanisms [6], and has reinforced this effort through training in implementation research [7] and operations research [8]...

A Changing Model for Developing Health Products for Poverty-Related Infectious Diseases

Piero L. Olliaro, Annette C. Kuesel, John C. Reeder Historical Profiles and Perspectives | published 08 Jan 2015 | PLOS Neglected Tropical Diseases 10.1371/journal.pntd.0003379

Applied Research for Better Disease Prevention and Control

Johannes Sommerfeld, Andrew Ramsay, Franco Pagnoni, Robert F. Terry, Jamie A. Guth, John C. Reeder Historical Profiles and Perspectives | published 08 Jan 2015 | PLOS Neglected Tropical Diseases 10.1371/journal.pntd.0003378

What Have We Learned from 40 Years of Supporting Research and Capacity Building?

John C. Reeder, Jamie A. Guth Historical Profiles and Perspectives | published 08 Jan 2015 | PLOS Neglected Tropical Diseases 10.1371/journal.pntd.0003355

Shaping the Research Agenda

Edith Certain, Robert F. Terry, Fabio Zicker Historical Profiles and Perspectives | published 08 Jan 2015 | PLOS Neglected Tropical Diseases 10.1371/journal.pntd.0003350

PLoS One

[Accessed 10 January 2015] http://www.plosone.org/
[No new relevant content]

PLoS Pathogens

http://journals.plos.org/plospathogens/ (Accessed 10 January 2015) [No new relevant content]

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

(Accessed 10 January 2015)
http://www.pnas.org/content/early/
[No new relevant content]

Pneumonia

Vol 5 (2014)

https://pneumonia.org.au/index.php/pneumonia/issue/current Special Issue "Pneumonia Diagnosis" [Reviewed earlier]

Public Health Ethics

Volume 7 Issue 3 November 2014
http://phe.oxfordjournals.org/content/current
Special Symposium on Dual Loyalities: Health Providers Working for the State
[Reviewed earlier]

Qualitative Health Research

February 2015; 25 (2) http://qhr.sagepub.com/content/current Special Issue: Responses to Treatment [New issue; No relevant content]

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

September 2014 Vol. 36, No. 3

http://www.paho.org/journal/index.php?option=com_content&view=article&id=151&Itemid=26 6&lang=en

[Reviewed earlier]

Risk Analysis

November 2014 Volume 34, Issue 11 Pages 1969–2062 http://onlinelibrary.wiley.com/doi/10.1111/risa.2014.34.issue-11/issuetoc [Reviewed earlier]

Science

9 January 2015 vol 347, issue 6218, pages 101-208 http://www.sciencemag.org/current.dtl Feature

On the trail of contagion

Kai Kupferschmidt*

Tracing contacts is crucial for stopping an Ebola outbreak. Public health workers need to find every patient, identify everyone they have interacted with, and monitor them for symptoms during the 21-day incubation period. But tracing contacts is a difficult and often frustrating job. Science joined a team in Bong County in Liberia that tried to locate a woman who had been in contact with two Ebola patients before they died; she reportedly fled to a remote village. The

tracing team made a harrowing and exhausting 9-hour trek through the jungle to find her—and came home empty-handed. Their quest highlights just how difficult it will be to end the West African Ebola epidemic.

Social Science & Medicine

Volume 126, <u>In Progress</u> (February 2015) <u>http://www.sciencedirect.com/science/journal/02779536/126</u> [Reviewed earlier]

Tropical Medicine and Health

Vol. 42(2014) No. 4 https://www.jstage.jst.go.jp/browse/tmh/42/4/_contents [Reviewed earlier]

Tropical Medicine & International Health

January 2015 Volume 20, Issue 1 Pages 1–119 http://onlinelibrary.wiley.com/doi/10.1111/tmi.2014.20.issue-1/issuetoc [Reviewed earlier]

Vaccine

Volume 33, Issue 3, Pages 403-486 (9 January 2015) http://www.sciencedirect.com/science/journal/0264410X/33/3 Editorial

Celebrating the ACIP at 50

Pages 403-404 Alan R. Hinman, Gregory A. Poland [No abstract] Discussion

The history of the United States Advisory Committee on Immunization Practices (ACIP)

Pages 405-414

L. Reed Walton, Walter A. Orenstein, Larry K. Pickering *Abstract*

The United States Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that develops written recommendations for use of vaccines licensed by the Food and Drug Administration (FDA) for the U.S. civilian population. Vaccine development and disease outbreaks contributed to the need for a systematized, science-based, formal mechanism for establishing national immunization policy in this country. Formed in 1964, the ACIP was charged with this role. The committee has undergone significant changes in structure and operational activities during its 50-year history. The ACIP works closely with many liaison organizations to develop its immunization recommendations, which are harmonized among key professional medical societies. ACIP vaccine recommendations form two immunization schedules, which are updated annually: (1) the childhood and adolescent immunization schedule and (2) the adult immunization schedule. Today, once ACIP recommendations are adopted by the Director of the

Centers for Disease Control and Prevention and the Secretary of the Department of Health and Human Services, these recommendations are published in Morbidity and Mortality Weekly Report (MMWR), become official policy, and are incorporated into the appropriate immunization schedule.

<u>Vaccination against varicella as post-exposure prophylaxis in adults: A quantitative assessment</u>

Original Research Article

Pages 446-450

Cécile Souty, Evelyne Boos, Clément Turbelin, Thierry Blanchon, Thomas Hanslik, Pierre-Yves Boëlle

Abstract

Background

Varicella can be severe in adults. When universal vaccination is not adopted, post-exposure prophylaxis has been recommended in adults with uncertain history of varicella to reduce the burden of the disease in adults, however its impact is not quantified.

Methods

We developed a Bayesian probabilistic framework to estimate the impact of post-exposure prophylaxis in adults. We hypothesized that post-exposure vaccination would be proposed only after varicella exposure in close relatives. Information regarding the nature of the culprit exposure was obtained from a sample of 221 adult varicella cases. The lifelong probability that adults aged 18 would be infected with varicella was determined using data from the French Sentinelles surveillance network. Estimates of post-exposure vaccination efficacy were then used to compute the number of cases and hospitalizations prevented in adults. Results

Familial exposure to varicella was reported by 81 adult cases out of 221. The probability of infection after exposure was 32%, so that six exposures on average were necessary to explain the observed cumulated lifetime incidence of varicella in non-immune 18 years old and over adults. Among the 35% of the 18 years old population with uncertain history of varicella, 11% would truly be non-immune. Post-exposure vaccination would prevent 26% of the cases (13 cases prevented per 100,000 adults per year) and 31% of the hospitalizations (0.2 hospitalizations prevented per 100,000 adults per year) if vaccination acceptance was 70%. An average of 16 adults would be vaccinated to avert one varicella case.

Conclusions

Post-exposure vaccination is associated with a substantial decrease in the burden of the disease in adults in a country where universal vaccination is not recommended. This quantitative information may help inform professionals to uphold the recommendation.

<u>Does correcting myths about the flu vaccine work? An experimental evaluation of the effects of corrective information</u>

Original Research Article

Pages 459-464

Brendan Nyhan, Jason Reifler

Abstract

Seasonal influenza is responsible for thousands of deaths and billions of dollars of medical costs per year in the United States, but influenza vaccination coverage remains substantially below public health targets. One possible obstacle to greater immunization rates is the false belief that it is possible to contract the flu from the flu vaccine. A nationally representative survey experiment was conducted to assess the extent of this flu vaccine misperception. We find that a substantial portion of the public (43%) believes that the flu vaccine can give you the flu. We

also evaluate how an intervention designed to address this concern affects belief in the myth, concerns about flu vaccine safety, and future intent to vaccinate. Corrective information adapted from the Centers for Disease Control and Prevention (CDC) website significantly reduced belief in the myth that the flu vaccine can give you the flu as well as concerns about its safety. However, the correction also significantly reduced intent to vaccinate among respondents with high levels of concern about vaccine side effects — a response that was not observed among those with low levels of concern. This result, which is consistent with previous research on misperceptions about the MMR vaccine, suggests that correcting myths about vaccines may not be an effective approach to promoting immunization.

Rotavirus vaccination compliance and completion in a Medicaid infant population

Original Research Article

Pages 479-486

Girishanthy Krishnarajah, Pamela Landsman-Blumberg, Elnara Eynullayeva Abstract

Highlights

- :: Rotavirus (RV) vaccination completion and compliance rates were assessed in the US.
- :: Completion rates and compliance were better for 2-dose than the 3-dose RV vaccine.
- :: DTaP vaccine was the greatest predictor of RV vaccination compliance.
- :: Higher completion rates and compliance might offer protection against RV infection.

Vaccine

Volume 33, Issue 2, Pages 277-402 (3 January 2015)

http://www.sciencedirect.com/science/journal/0264410X/33/2

Commentary

The need for a multi-disciplinary perspective on vaccine hesitancy and acceptance

Pages 277-279

Caroline M. Poland, Emily K. Brunson

[No abstract]

Factors associated with HPV awareness among mothers of low-income ethnic minority adolescent girls in Los Angeles

Original Research Article

Pages 289-293

Beth A. Glenn, Jennifer Tsui, Rita Singhal, Leah Sanchez, Narissa J. Nonzee, L. Cindy Chang, Victoria M. Taylor, Roshan Bastani

Abstract

Among caregivers of adolescent girls, awareness of human papillomavirus (HPV) is strongly associated with vaccine uptake. Little is known, however, about the predictors of HPV awareness among low-income ethnic minority groups in the U.S. The purpose of this study is to understand demographic factors associated with HPV awareness among low-income, ethnic minority mothers in Los Angeles County. We conducted a cross-sectional study of caregivers of adolescent girls through the Los Angeles County Department of Public Health Office of Women's Health's hotline. The majority of the participants were foreign-born (88%), one quarter lacked a usual source of care, and one quarter lacked public or private health insurance for their daughter. We found that one in three participants had never heard of HPV or the vaccine. Mothers that were unaware of HPV were significantly more likely to conduct the interview in a language other than English and to lack health insurance for their daughters. HPV vaccine awareness was much lower in our caregiver sample (61%) than in a simultaneous national survey of caregivers (85%). The associations between lack of awareness and use of a language

other than English, as well as lack of health insurance for their daughter indicate the need for HPV vaccine outreach efforts tailored to ethnic minority communities in the U.S.

Vaccine

Volume 33, Issue 1, Pages 1-276 (1 January 2015)

http://www.sciencedirect.com/science/journal/0264410X/33/1

Editorial

Recommendations for strengthening NITAG policies in developed countries Pages 1-2

G.W. Ricciardi, M. Toumi, G. Poland

Vaccination constitutes one of the most significant public health advancements protecting millions of people from infectious diseases worldwide and contributing to the socio-economic development of nations on a global scale. Preventative in nature, vaccines have been traditionally used with the aim of directly avoiding or reducing overall incidence, morbidity, and mortality in healthy individuals, proving vaccination is a highly cost-effective public health intervention [1]. Yet, time to effective populations' access to new vaccines is heterogeneous and lengthy in developed countries, with an average of 6.4 years between European Marketing Authorization and effective populations' access to new vaccines [2]. The delay in access is mainly driven by the time taken by National Immunization Technical Advisory Groups (NITAG) to issue vaccination recommendations guiding the executive policy-decisions [2]. Ricciardi et al. reported the heterogeneity in NITAG terms of reference and analytical decision frameworks that may contribute to the disparity in access to vaccination and immunization programs across developed countries [3]:

- :: In a study of 13 countries, publicly available information on NITAGs' policies and processes was very limited in most countries, but more documented in the UK, US and Germany.
 :: The decision analysis frameworks that are critical for transparent, structured, reproducible and reliable decision-making, were available for a limited number of NITAGs with only two countries (Germany and the US) using a detailed and standardized methodology for reliable, robust, and reproducible assessments (the Grades of Recommendation, Assessment, Development and Evaluation GRADE) [4], [5], [6] and [7].
- :: The lack of transparency in NITAGs' interaction with the general public and healthcare professionals deserves improvement. Few NITAGs published their meeting agendas and minutes and only the US had open meetings.

<u>Development of a quality framework for models of cervical screening and its</u> <u>application to evaluations of the cost-effectiveness of HPV vaccination in developed</u> countries

Review Article

Pages 34-51

Leonardo Simonella, Karen Canfell

Abstract

Background

HPV vaccination has now been introduced in most developed countries, but this has occurred in the context of established cervical cancer screening mechanisms which provide population-level protection against the most common HPV-related cancer. Therefore, estimating the cost-effectiveness of HPV vaccination to further reduce HPV-related disease depends in large part on the estimation of the effectiveness of the cervical screening 'background'. The aim of this study was to systematically review and assess methods for simulating cervical screening in decision analytic models used for evaluation of HPV vaccination.

Methods

Existing quality frameworks for economic models were extended to develop a specific quality framework for models of cervical screening. This involved domains for model structure, parameterisation (data sources) and validation (consistency). A systematic review of economic evaluations of HPV vaccination was then conducted, and assessment of cervical screening model components was then performed via application of the new quality framework. Results

Generally, models took into account population-level cervical screening participation, but were inconsistent in their approach to modelling abnormal smear management, diagnostic evaluation and treatment of precancerous disease. There was also considerable variability in the accuracy of modelling clinical pathways and the scope of validation performed for screening-related outcomes, with focus directed towards cervical cancer targets. Only a few models comprehensively validated against observed pre-cancerous abnormalities. Conclusion

Models of HPV vaccination in developed countries can be improved by further attention to the 'background' modelling of secondary protection via cervical screening. The quality framework developed for this review can be used to inform future HPV vaccination evaluations, including evaluations of the cost-effectiveness of male vaccination and next generation HPV vaccines, and to assess models used to evaluate new cervical screening technologies and recommendations.

<u>Twenty-five years of the WHO vaccines prequalification programme (1987–2012):</u>
<u>Lessons learned and future perspectives</u>

Review Article Pages 52-61

Nora Dellepiane, David Wood

Abstract

The World Health Organization (WHO) vaccines prequalification programme was established in 1987. It is a service provided to United Nations procurement agencies to ensure that the vaccines supplied through these agencies are consistently safe and effective under conditions of use in national immunization programmes. This review describes the purpose and aims of the programme, its evolution during 25 years of existence, its added value, and its role in the context of the WHO strategy to ensure the global availability of vaccines of assured quality. The rationale for changes introduced during the implementation of the programme is provided. The paper also discusses the resources involved, both human and financial, its performance, strengths and weaknesses and steps taken to maximize its efficiency. This historical perspective is used to inform proposed future changes to the service.

What predicts postpartum pertussis booster vaccination? A controlled intervention trial

Original Research Article

Pages 228-236

Elizabeth Helen Hayles, Spring Chenoa Cooper, Nicholas Wood, John Sinn, S. Rachel Skinner Highlights

- :: We immunised 70% of susceptible postpartum mothers, demonstrating that information, using either gain or loss-framing or standard factsheet, is effective at increasing uptake.
- :: Perceived vaccine benefits, a vaccine recommendation and pre-existing vaccine intentions independently predicted pertussis vaccine uptake.
- :: Postpartum pertussis booster vaccination can achieve high coverage (from 23% to 77%) when implemented in the hospital setting.

Vaccine: Development and Therapy

(Accessed 10 January 2015)

http://www.dovepress.com/vaccine-development-and-therapy-journal

[No new relevant content]

Vaccines — Open Access Journal

(Accessed 10 January 2015)

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

The Potential Impact of Preventive HIV Vaccines in China: Results and Benefits of a Multi-Province Modeling Collaboration

by <u>Thomas Harmon</u>, <u>Wei Guo</u>, <u>John Stover</u>, <u>Zunyou Wu</u>, <u>Joan Kaufman</u>, <u>Kammerle Schneider</u>, <u>Li</u> Liu, Liao Feng and Bernard Schwartländer

Vaccines **2015**, *3*(1), 1-19; doi: 10.3390/vaccines3010001 - published 5 January 2015 *Abstract:*

China's commitment to implementing established and emerging HIV/AIDS prevention and control strategies has led to substantial gains in terms of access to antiretroviral treatment and prevention services, but the evolving and multifaceted HIV/AIDS epidemic in China highlights the challenges of maintaining that response. This study presents modeling results exploring the potential impact of HIV vaccines in the Chinese context at varying efficacy and coverage rates, while further exploring the potential implications of vaccination programs aimed at reaching populations at highest risk of HIV infection. A preventive HIV vaccine would add a powerful tool to China's response, even if not 100% efficacious or available to the full population.

Value in Health

Volume 17, Issue 8, p757-896 December 2014 http://www.valueinhealthjournal.com/current [Reviewed earlier]

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

Journal of Women's Health, Issues & Care

2014, 3:6

Issues Care 2014, 3:6

http://dx.doi.org/10.4172/2325-9795.1000170

[PDF] <u>Nuances in Inoculation: Protecting Positive Attitudes toward the HPV Vaccine</u> & the Practice of Vaccinating Children

Norman C. H. Wong1* and Kylie J. Harrison2

Abstract

This study examined the use of two different inoculation messages in conferring resistance to persuasive messages attacking vaccinations. A three-phase experiment involving 212 participants was conducted to determine if young women who held positive attitudes toward

the HPV vaccine/practice of vaccinating children could be inoculated against messages attacking

the HPV vaccine/practice of vaccinating children. Results found that inoculation treatments aimed at protecting positive attitudes toward the practice of vaccinations in general were as effective at thwarting attacks on the HPV vaccine as the use of inoculation treatments aimed directly at protecting positive attitudes about the HPV vaccine itself. In addition to traditional inoculation outcomes (e.g., attitudes, counterarguing), the results revealed that inoculation treatments also had an impact on other outcomes as well (e.g., perceived vaccine safety, behavioral intentions).

Journal of School Health

Vol 85 Issue 2

School Nurses' Knowledge, Attitudes, Perceptions of Role as Opinion Leader, and Professional Practice Regarding Human Papillomavirus Vaccine for Youth

Brittany L. Rosen PhD, CHES Assistant Professor1,*, Patricia Goodson PhD Professor2, Bruce Thompson PhD Distinguished Professor3 and Kelly L. Wilson PhD, CHES Associate Professor4 Article first published online: 7 JAN 2015

DOI: 10.1111/josh.12229

ABSTRACT BACKGROUND

Because human papillomavirus (HPV) vaccine rates remain low, we evaluated US school nurses' knowledge, attitudes, perceptions of their role as opinion leaders, and professional practice regarding HPV vaccine, and assessed whether knowledge, attitudes, and perceptions of being an opinion leader influenced their professional practice regarding the HPV vaccine.

METHODS

We used a cross-sectional design by recruiting members from the National Association of School Nurses. All participants (N = 505) were e-mailed a survey designed for this study. Structural equation modeling (SEM) tested direct and indirect effects. RESULTS

Overall, school nurses had knowledge about HPV and the vaccine, and positive attitudes toward the vaccine. They had less-than-enthusiastic perceptions of their role as opinion leaders regarding the vaccine and implemented few activities related to providing vaccine information. The model revealed a good fit ($\chi 2 = 20.238$ [df = 8, p < .01]), with knowledge directly related to attitudes, attitudes directly related to perceptions and practice, and perceptions directly affecting practice. In our model, perceptions functioned as a partial mediator. CONCLUSIONS

To enhance school nurses' practice regarding the HPV vaccine, focus should be on increasing positive attitudes toward the vaccine and strengthening perceptions of their role as opinion leaders

Materia Socio Medica

2014; 26(6): 382-384

doi: 10.5455/msm.2014.26.382-384

[PDF] The Impact of War on Vaccine Preventable Diseases

Zarema Obradovic, Snjezana Balta, Amina Obradovic, Salih Mesic. *Abstract*

Introduction: During the war in Bosnia and Herzegovina, which lasted from 1992-1995, the functioning of all sectors was disturbed, including the health sector. The priority of the heath

sector was treatment and less attention was paid to prevention, and this applies also to the program of implementation of obligatory immunization, as one of the most important prevention measures. This program was conducted with difficulty and sometimes was completely interrupted because of the lack of necessary vaccines and the inability of adequate maintenance of the cold chain. It was difficult and sometimes completely impossible to bring children to vaccination. Because of these problems, a great number of children stayed unvaccinated so they suffered from vaccine-preventable diseases several years after the war.

Materials and methods: This is a retrospective epidemiological study. We analyzed data from January 1994 to July 2014 in Canton Sarajevo, and data about measles outbreak in 2014.

Results: In the period from January 1994 to July 2014, 3897 vaccine-preventable diseases were registered in Canton Sarajevo. Among them measles, rubella and mumps were the most frequent. In March 2014, measles outbreak was registered. Almost all cases are unvaccinated (99%) and 43% of all cases are connected with failure of vaccination during the war.

Conclusion: During the war, routine immunization program was disrupted in Bosnia and Herzegovina (also in Canton Sarajevo). The consequences are presented as vaccine preventable diseases cases.

Applied and Environmental Microbiology

January 2015, volume 81, issue 2

<u>Environmental Surveillance of Poliovirus in Sewage Water around the Introduction</u>

<u>Period of Inactivated Polio Vaccine in Japan</u>

<u>Tomofumi Nakamura1,2, Mitsuhiro Hamasaki2, Hideaki Yoshitomi2, Tetsuya Ishibashi2, Chiharu Yoshiyama2, Eriko Maeda2, Nobuyuki Sera2*</u> and <u>Hiromu Yoshida1</u>
<u>ABSTRACT</u>

Environmental virus surveillance was conducted at two independent sewage plants from urban and rural areas in the northern prefecture of the Kyushu district, Japan, to trace the polioviruses (PVs) within communities. Consequently, 83 PVs were isolated over a 34-month period from April 2010 to January 2013. The frequency of PV isolation at the urban plant was 1.5-times higher than that at the rural plant. Molecular sequence analysis of the viral VP1 gene identified all three serotypes among the PV isolates the most prevalent serotype being type 2 (46%). Nearly all poliovirus isolates exhibited more than one nucleotide mutation from the Sabin vaccine strains. During this study, inactivated poliovirus vaccine (IPV) was introduced for routine immunization on September 1, 2012, replacing the live oral poliovirus vaccine (OPV). Interestingly, the frequency of PV isolation from sewage waters declined before OPV cessation at both sites. Our study highlights the importance of environmental surveillance to detect the excretion of PVs from an OPV-immunized population in a highly sensitive manner, during the OPV to IPV transition period.

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.

Al Jazeera

http://www.aljazeera.com/Services/Search/?q=vaccine

Accessed 10 January 2015

[No new, unique, relevant content]

AP (Associated Press)

http://hosted.ap.org/dynamic/fronts/HOME?SITE=AP

Accessed 10 January 2015

[No new, unique, relevant content]

The Atlantic

http://www.theatlantic.com/magazine/ Accessed 10 January 2015 [No new, unique, relevant content]

BBC

http://www.bbc.co.uk/ Accessed 10 January 2015 [No new, unique, relevant content]

Brookings

http://www.brookings.edu/ Accessed 10 January 2015 [No new, unique, relevant content]

Council on Foreign Relations

http://www.cfr.org/ Accessed 10 January 2015 [No new, unique, relevant content]

The Economist

http://www.economist.com/ Accessed 10 January 2015 [No new, unique, relevant content]

Forbes

http://www.forbes.com/ Accessed 10 January 2015 'Nigeria Is Paving The Way For A Polio-free Africa' Forbes | 8 January 2015 "Nigeria is paving the way for a polio-free Africa," according to John Vertefeuille, team lead for Nigeria at the Centers for Disease Control. With the World Health Organization reporting no cases of polio in Nigeria since July 24, 2014 and the last in Africa reported in August, Vertefeuille's enthusiasm is well-founded...

Foreign Affairs

http://www.foreignaffairs.com/ Accessed 10 January 2015 [No new, unique, relevant content]

The Guardian

http://www.guardiannews.com/ Accessed 10 January 2015 [No new, unique, relevant content]

The Huffington Post

http://www.huffingtonpost.com/ Accessed 10 January 2015 [No new, unique, relevant content]

Le Monde

Accessed 10 January 2015
http://www.lemonde.fr/
[No new, unique, relevant content]

New Yorker

http://www.newyorker.com/ Accessed 10 January 2015 [No new, unique, relevant content]

New York Times

http://www.nytimes.com/ Accessed 10 January 2015 Effort on Ebola Hurt WHO Chief 6 January 2015

Reuters

http://www.reuters.com/ Accessed 10 January 2015

IMF says preparing \$150 mln in aid to three main Ebola-hit nations

Reuters | 9 January 2015

The International Monetary Fund is preparing \$150 million in additional support to Liberia, Sierra Leone and Guinea, the countries at the heart of the Ebola epidemic, the Fund's representative in Liberia told Reuters on Thursday.

Wall Street Journal

http://online.wsj.com/home-page?_wsjregion=na,us&_homepage=/home/us Accessed 10 January 2015 [No new, unique, relevant content]

Washington Post

http://www.washingtonpost.com/ Accessed 10 January 2015 [No new, unique, relevant content]

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Ebola/EVD: Additional Coverage

UNMEER [UN Mission for Ebola Emergency Response] @UNMEER #EbolaResponse

Editor's Note: UNMEER's <u>website</u> is aggregating and presenting content from various sources including its own External Situation Reports, press releases, statements and other format. We present a composite below from the week ending 10 January 2015. We also note that 1) a regular information category in these reports – human rights – has apparently eliminated as it no longer appears in any of these week's updates, and 2) the content level of these reports has, in our view, become less informative and less coherent over the last several week cycles.

UNMEER External Situation Reports

UNMEER External Situation Reports are issued daily (excepting Saturday) with content organized under these headings:

- Highlights
- Key Political and Economic Developments
- Human Rights
- Response Efforts and Health
- Logistics
- Outreach and Education
- Resource Mobilisation
- Essential Services
- Upcoming Events

The "Week in Review" will present highly-selected elements of interest from these reports. The full daily report is available as a pdf using the link provided by the report date.

:: **09 Jan 2015** UNMEER External Situation Report

Key Political and Economic Developments

1. Guinea is facing a fuel shortage which is impacting the Ebola response. The UNMEER Field Crisis Manager for Macenta reported that on 8 January the Guinea Red Cross was unable to transport a suspected case to the Ebola Treatment Centre (ETC) due to the fuel shortage. Reports indicate that local authorities have been working on to support the French Red Cross at the ETC. In addition the UNMEER Field Crisis Manager for N'zérékoré, Lola and Yomou has reported that fuel supplies are down to 5,000 liters (10 days of supply) at the Ebola Treatment Unit (ETU) and that radio stations which broadcast sensitization messages have not been working for 4 days.

Response Efforts and Health

5. The planned launch of the campaign "Zero Ebola in 60 days" (refer to Sitrep of 5 January) which was to be held in Forécariah prefecture, Guinea on 10 January has been put on hold due to the continuing resistance of the communities to EVD response in that area. According to WHO, on 6 January, there were 31 sub-prefectures in the country where EVD response efforts were facing community resistance.

Resource Mobilisation

- 9. The OCHA Ebola Virus Outbreak Overview of Needs and Requirements, now totaling USD 1.5 billion, has been funded for USD 1.16 billion, which is around 77% of the total ask.
- 10. The Ebola Response Multi-Partner Trust Fund currently has USD 134.9 million in commitments. In total USD 140 million has been pledged.

Essential Services

13. In addition to the procurement of 15,000 thermo-guns (refer to Sitrep of 6 January), UNICEF initiated procurement of sanitation and hygiene supplies (hand-washing buckets, sprayers, protective equipment for cleaning) to ensure that all 5,181 Liberian schools have the essential hygiene and hand-washing materials to promote safe learning environments and to be in compliance with the endorsed protocols upon reopening.

:: 8 Jan 2015 UNMEER External Situation Report

Key Political and Economic Developments

- 1. SRSG Ould Cheikh Ahmed continued his familiarization visit to Liberia on 7 January, and conducted a field mission to Robertsport and Sinje in Grand Cape Mount county, accompanied by Special Envoy David Nabarro, WHO Assistant Director-General Bruce Aylward and UNMEER Liberia's ECM Peter Graaff. The delegation also included the Presidential Advisor on EVD and the Deputy Minister for Health in charge of the Incident Management System (IMS). In light of the recent flare-ups in EVD transmission in the county, and the risk of cross-border transmission along the frontier with Sierra Leone, the UNMEER leadership invited the county's traditional and religious leaders, along with county health and security officials, for a series of meetings. The SRSG underlined the importance of national ownership to defeat the epidemic. He also emphasized the need to respect local communities and their values when implementing internationally-sponsored support activities, especially with regard to safe and dignified burials. He reiterated that coordinating activities at the district levels was essential. During the County Health Team meeting, the participants discussed the evolution of the epidemic in the county, as well as the emergency measures taken in response to the recent flare-up. Participants highlighted key challenges, including inadequate monitoring of cross-border traffic along the Sierra Leone frontier, ongoing traditional practices, secret burials, community pockets of denial and resistance, as well as lack of motivation among the response teams. The delegation also visited the recently opened Ebola Treatment Unit (ETU) in Sinje, before the SRSG is today in Sierra Leone.
- 2. On 7 January, the national trade unions in Guinea called off the general strike throughout the country, which had started on 6 January (refer to UNMEER Sitrep of 6 January), after reaching an agreement on salary increases with the Government.

 Response Efforts and Health
- 3. To date, the UNICEF-led Family Tracing and Reunification (FTR) network in Sierra Leone has identified 14,766 children as being directly affected by the Ebola crisis (7,410 girls and 7,356 boys), with 7,938 children having lost one or both parents to EVD and 1,578 being unaccompanied or separated from their caregiver. The Ministry of Social Welfare, Gender and

Children's Affairs' (MSWGCA) figures have jumped markedly from 24 – 31 December as child protection networks strengthened across the country.

Outreach and Education

13. Due to the persistent community resistance in 31 sub-prefectures in Guinea to EVD response efforts, WHO commissioned a number studies on this topic that will be collated as soon as possible.

Essential Services

14. Following reported cases of measles in Lofa county, Liberia, UNICEF supported periodic intensification of routine immunization against measles throughout the country. So far, the routine immunization has been completed in 8 counties, is underway in 4 and is about to begin in the last 3 counties (namely Maryland, Bong and River Gee). This is activity is being implemented in lieu of an immunization campaign, which is not recommended in the Ebola context and aims at rapidly reducing the number of unimmunized children against measles.

:: 07 Jan 2015 UNMEER External Situation Report

Key Political and Economic Developments

- 1. As part of a visit to the three most affected countries, President Ould Abdel Aziz of the Islamic Republic of Mauritania and current Chair of the African Union (AU), arrived in Guinea yesterday and met with President Condé. The President pledged USD 400,000 to help Guinea in its fight against EVD, and also announced that Air Mauritania would operate flights to Guinea. The Chair of the AU travelled to Liberia today.
- 2. Today, President Mahamadou Issoufou of Niger and President Boni Yayi of Benin are jointly visiting Guinea to demonstrate their support in the fight against EVD. Response Efforts and Health
- 4. A Community Transit Centre (CTCom) was burnt down yesterday in Bossou, Lola prefecture, Guinea. The centre, which was still under construction, would have been one of the first functional CTCom in Guinea. This act of arson is likely to be due to the continuing resistance of the local community to EVD response efforts.
- 5. The Ministry of Education (MoE), UNICEF and education partners have been working together in preparation of the reopening of schools in Guinea. In this regard, UNICEF plans to reach 7,055 schools (56% of schools at all levels) and 1.4 million children (53% of all school children) with 16,000 school hygiene kits (containing buckets and soap). In addition, the Islamic Development Bank (IDB) confirmed its commitment to support the provision of Thermoflashes for schools in Guinea. An IDB consultant is scheduled to arrive in Conakry on 9 January to help implement this project.

Outreach and Education

18. UNICEF signed a partnership agreement with Search for Common Ground to support the Liberian Ministry of Education's (MoE) Emergency Radio Education program in light of closed schools across the country. In collaboration with MoE's radio content development team, Search for Common Ground will expand broadcast coverage across all 15 counties in Liberia, integrating targeted programs on peacebuilding and education to build resilience amongst listeners during times of crisis.

:: 06 Jan 2015 UNMEER External Situation Report

Key Political and Economic Developments

1. Following an impasse in the negotiations between the Government of Guinea and six national trade unions, including the public health workers union, on salary increases and other

demands, the unions called for a general strike throughout the country as of today. Limited demonstrations and road closures have been observed in Conakry.

- 2. Following the announcement by the President of Sierra Leone on New Year's day of his intention to reopen schools soon, the Governments of Liberia and Guinea similarly announced that schools would reopen. While Guinea did not provide a specific date, President Ellen Johnson Sirleaf provided 2 February as the target date.
- 9. In support of the Minister of Education's school reopening plan in Liberia, UNICEF initiated procurement of infrared thermometers for every Liberian school (15,000 thermometers) to ensure effective health screening of all individuals upon entry to school campuses.
- 10. In Sierra Leone, UNICEF, in partnership with the National Ebola Response Centre (NERC), the Ministry of Health and Sanitation, and the Centre for Disease Control (CDC), continues the national scale up of trainings at all 1,188 Public Health Units (PHUs) in the country on Infection Prevention and Control (IPC) and the screening of suspected Ebola patients. As of 27 December, a total of 4,368 health personnel and 2,698 support staff including cleaners and security personnel have benefitted from IPC trainings.
- 11. Following the registration of 13,608 households in 9 chiefdoms within 29 Ebola affected communities in Kono District, Sierra Leone, which were identified as major EVD hotspots, WFP has begun the delivery of over 1,000 metric tons of assorted food commodities to quarantined communities. Food distributions will be undertaken by World Vision. In Waterloo, Western Area Rural, Sierra Leone, WFP and its cooperating partner CIDO are also continuing general food distributions to meet the needs of over 47,000 households where high EVD rates have been identified. Since mid-December over 25,000 households have received one month rations.

:: 05 Jan 2015 UNMEER External Situation Report

Key Political and Economic Developments

1. The New Head of UNMEER, SRSG Ismail Ould Cheikh Ahmed, assumed his functions on 3 January. In a joint townhall meeting with outgoing SRSG Banbury, SRSG Ould Cheikh Ahmed praised the achievements of all Ebola response partners, but also noted challenges ahead. He stressed that "this is a global crisis. We definitely have a difficult time ahead of us, but we can achieve our goal of zero cases," said Ould Cheikh Ahmed. "This is within our reach, but we should not be complacent. We need to keep going until we don't have even one case, because even one case is too many". Together with the Special Envoy on Ebola, Dr. David Nabarro, SRSG Ould Cheikh Ahmed will be visiting Liberia, Sierra Leone this week and Guinea shortly after.

Response Efforts and Health

- 1. In Guinea, the National Coordinator briefed key response partners on 2 January on the launch of the campaign "Zero Ebola in 60 days". Working groups have in recent days developed action plans for the campaign across the main lines of intervention: surveillance, case management, infection prevention and control, community engagement and social mobilization, safe burials and coordination. The first step of the campaign will involve the fielding of teams including experts from each line of action in six regions of the country for one or two weeks starting 6 January. The purpose of the missions will be for each team to assess the response efforts at the local level and develop with each prefecture the coordination of a local plan of action mirroring the national plan of action.
- 2. The total number of children registered as orphaned by EVD in Liberia is 4,128. All registered orphans are currently receiving follow-up and psychosocial support. More than 250 volunteer contact tracers trained and engaged by UNICEF are reporting cases of children orphaned or otherwise affected by EVD. UNICEF is working to ensure that children who have

lost their parents due to EVD continue to receive care through a kinship arrangement, to prevent them from becoming institutionalized in an orphanage. To strengthen this, UNICEF provides onetime cash transfers to families that take the responsibility to care for orphaned children of relatives.

Outreach and Education

- 13. According to WHO, on 31 December, there were 25 sub-prefectures in Guinea where EVD response efforts were facing community resistance. These sub-prefectures are located in the prefectures adjacent to Conakry (Dubreka, Forécariah, Coyah and Kindia), in the Forest Region (Kissidougou, Guéckédou, Nzérékoré), in Upper Guinea (Dabola) and in Western Guinea (Télimélé and Labé).
- 14. On 1 January, a team of the Guinean Red Cross was assaulted by the local community in Kindia, Guinea resulting in one injured Red Cross volunteer and one vandalized vehicle. According to the IFRC, the team had travelled to Kindia to conduct a safe burial and to transfer suspected cases. The prefectural coordination solicited the support of the military which proceeded to arrest two persons suspected of taking part in the assault.

* * *

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Development Program; the <u>International Vaccine Institute</u> (IVI); the <u>Bill & Melinda Gates</u>

Foundation; industry resource members Janssen, Pfizer, and Sanofi Pasteur U.S. (list in formation), and the Developing Countries Vaccine Manufacturers Network (DCVMN).

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

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