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Vaccines and Global Health: The Week in Review
7 March 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.*

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EBOLA/EVD [to 7 March 2015]
Public Health Emergency of International Concern (PHEIC); "Threat to international peace and security" (UN Security Council)

WHO: Ebola Situation Report - 4 March 2015
Corrigendum as of 6 March 2015
[Excerpt; Editor's text bolding]
SUMMARY
:: **A total of 132 new confirmed cases of Ebola virus disease (EVD) were reported in the week to 1 March, an increase on the previous week (99 new cases).** Liberia reported no new confirmed cases this week, the first time since the week of 26 May 2014. The weekly number of confirmed cases has increased in both Sierra Leone and Guinea. Transmission remains widespread in Sierra Leone, which reported new confirmed cases in 8

districts during the week to 1 March. In Guinea, Forecariah and Conakry reported a marked increase in case numbers compared with the previous week.

:: Guinea reported 51 new confirmed cases in the week to 1 March, compared with 35 cases the previous week. Cases continue to arise from unknown sources with only 49% of cases arising from registered contacts. Seven prefectures reported new cases, with the largest number of new confirmed cases reported from 3 neighbouring western prefectures: Conakry (17 cases), Coyah (5 cases), and Forecariah (23 cases). Macenta also reported 2 new confirmed cases, a district that has not reported a confirmed case for 4 weeks. Low levels of transmission continue in the eastern prefecture of Lola (1 new case), bordering Côte d'Ivoire.

:: Sierra Leone reported 81 new confirmed cases from 8 districts in the week to 1 March. A previously reported cluster of cases in the Aberdeen fishing community of the capital, Freetown, has seeded outbreaks in other districts, notably Bombali which reported 22 new confirmed cases. There were 26 new confirmed cases in Freetown and 16 new cases in Port Loko over the same period.

:: Liberia has reported no new confirmed cases this week. Contacts from the last known chain of transmission, in the St Paul's Bridge district of Monrovia, are being monitored. In the week to 1 March, 277 samples were tested for EVD nationwide, no new test results were positive.

:: The number of confirmed EVD deaths occurring in the community in Guinea and Sierra Leone remains high, suggesting that the need for early isolation and treatment is not yet understood, accepted or acted upon. In Guinea in the week to 1 March over half (53%: 17 out of 32) of reported confirmed deaths occurred in the community, an increase from 42% the previous week (9 out of 21). In Sierra Leone, 16% of confirmed EVD deaths occurred in the community in the week to 1 March, compared with 21% the previous week.

:: Unsafe burials continue to occur, with 16 reports of unsafe burials in both Guinea and Sierra Leone, respectively, during the weeks to 1 March and to 22 February.
Laboratories in Guinea, Liberia and Sierra Leone processed 270, 277 and 1531 samples, respectively, in the week to 1 March.

:: **Mindful of the risk of cross border transmission, delegations from Guinea, Mali and Senegal met on 25-26 February 2015 and agreed to strengthen cross-border cooperation in case management (including the sharing of laboratory resources), community-based surveillance, risk communication and information sharing, and screening at border crossings.**

:: In the week to 1 March, 1 new health worker infection was reported Guinea, bringing the total of health worker infections reported across the three most-affected countries since the start of the outbreak to 839, with 491 deaths.

COUNTRIES WITH WIDESPREAD AND INTENSE TRANSMISSION

:: **There have been over 23,900 reported confirmed, probable, and suspected cases cases of EVD in Guinea, Liberia and Sierra Leone (table 1), with over 9800 reported deaths** (outcomes for many cases are unknown). A total of 51 new confirmed cases were reported in Guinea, 0 in Liberia, and 81 in Sierra Leone in the 7 days to 1 March.

:: The total number of confirmed and probable cases is similar in males and females (table 2). Compared with children (people aged 14 years and under), people aged 15 to 44 are approximately three times more likely to be affected. People aged 45 and over are nearly four times more likely to be affected than children.

:: A total of 839 confirmed health worker infections have been reported in the 3 intense-transmission countries; there have been 491 reported deaths…

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Ebola vaccine efficacy trial ready to launch in Guinea

Joint news release WHO/MSF/NIPH

5 March 2015 ¦ GENEVA - Based on promising data from initial clinical trials in late 2014, WHO with the Health Ministry of Guinea, Médecins Sans Frontières (MSF), Epicentre and The Norwegian Institute of Public Health (NIPH), will launch a Phase III trial in Guinea on 7 March to test the VSV-EBOV vaccine for efficacy and effectiveness to prevent Ebola. The vaccine was developed by the Public Health Agency of Canada. A second vaccine will be tested in a sequential study, as supply becomes available.

"We have worked hard to reach this point," said WHO Director-General, Dr Margaret Chan. "There has been massive mobilization on the part of the affected countries and all partners to accelerate the development and availability of proven interventions. If a vaccine is found effective, it will be the first preventive tool against Ebola in history."

Vaccination will take place in areas of Basse Guinée, the region that currently has the highest number of cases in the country. The trial strategy adopted will be "ring vaccination", based on the approach used to eradicate smallpox in the 1970s. This involves the identification of a newly diagnosed Ebola case – the "index case" – and the tracing of all his/her contacts. The contacts are vaccinated if they give their consent.

"The Ebola epidemic shows signs of receding but we cannot let down our guard until we reach zero cases," said Assistant Director-General Marie-Paule Kieny, who leads the Ebola Research and Development effort at WHO. "An effective vaccine to control current flare-ups could be the game-changer to finally end this epidemic and an insurance policy for any future ones."

The objectives of the trial are two-fold: to assess if the vaccine protects the contacts who were vaccinated and if vaccinating the contacts will create a buffer - or ring of protected individuals - around the index case to prevent further spread of the infection. Vaccination will also be proposed to frontline workers in the area where the trial will take place.

Canadian governmental institutions are supporting the trial through the provision of critical training and support to the African research teams conducting the trial, in addition to scientific advice.

In the last six months WHO has convened a series of emergency consultations with scientists, ethicists, regulators and policy makers to identify potential preventive and therapeutic products

to help stem the epidemic. Canada's VSV and GSK cAd3 vaccines quickly emerged as promising tools due to prior successful studies on non-human primates.

"For more than a year we have been racing around the clock to stop the epidemic from spreading further," explains Bertrand Draguez, Medical Director at MSF.

"We need to ensure that we continue our efforts to identify infection cases and follow up on their contacts, and in parallel keep promoting R&D for treatments, diagnostics and vaccines.

This epidemic remains unpredictable. We don't know when it will end, and that's why it remains crucial for us to keep focusing our efforts on developing a vaccine capable of protecting the population in this epidemic and any future ones. Frontline workers and the contacts of infected patients will be enrolled, if they consent, in the vaccine study."

"Participation of the community in the study areas in Guinea is vital to enable the successful assessment of this vaccine," stresses John-Arne Røttingen, NIPH, and chair of the study steering group. "The study process has ensured the inclusion of Guinean investigators since its inception, and is a response to a request from Guinean authorities."

Since September 2014, the two most advanced Ebola vaccines have been evaluated in about 15 countries in Africa, Europe and North America. The testing timelines were considerably accelerated through the simultaneous organization of multiple trials and emergency procedures to expedite data sharing and analysis between the investigators and manufacturers. The VSV-EBOV vaccine was selected for the planned trial based on a framework of parameters developed by the WHO Scientific and Technical Advisory Committee on Ebola Experimental interventions (STAC-EE). Criteria included acceptable safety profile, induction of appropriate immune responses, including neutralizing antibodies, and the timely availability of sufficient supplies of vaccine doses.

Further measures were taken to accelerate the testing process by organizing multi-country emergency assessments, joint ethical and regulatory reviews of trial protocols and clearing of regulatory hurdles. For the Guinea trial, the Guinea National Regulatory Authority with support from Health Canada jointly reviewed the trial protocol.

WHO, UNICEF, US Centers for Disease Control (CDC), the Bill and Melinda Gates Foundation and GAVI (the Global Vaccine Alliance) are collaborating with the affected countries to develop plans and strategies for large-scale introduction, should this be needed. The vaccines' manufacturers have assured that enough vaccine will be available in the coming months. Financial resources are in place to procure and make vaccines available to the Ebola affected countries. Millions of doses will be funded by GAVI, whose Executive Board approved a US$ 300 million funding envelope in December 2014. There are also U$ 90 million earmarked to support the deployment of the vaccine(s).

Note to editors:
The vaccines: VSV-EBOV was developed by the Public Health Agency of Canada. The vaccine was licenced to NewLink Genetics, and on November 24, 2014, NewLink Genetics and Merck announced their collaboration on the vaccine. GlaxoSmithKline (GSK) developed the cAd3-ZEBOV vaccine in collaboration with the United States National Institutes for Health.

Ring vaccination was selected, with a design allowing part of the rings (contacts of the newly diagnosed Ebola case) to be vaccinated immediately after the case is detected, while other rings will be vaccinated 3 weeks later (delayed ring). This design allows for all contacts to be vaccinated by the end of the study, albeit with a short delay for some of them, rather than the standard alternative to use a placebo.

The trial design was developed by an international group of experts from Canada, France, Guinea, Norway, Switzerland, United Kingdom, United States, and WHO. The group included Professor Donald Henderson, who led the WHO smallpox eradication effort.

The partners: The Guinea Ebola vaccine trial is a coordinated effort among numerous international partners. The regulatory sponsor of the study is the World Health Organization (WHO): implemented by the Ministry of Health of Guinea, Médecins sans Frontières (MSF), EPICENTRE, the Norwegian Institute of Public Health and WHO. The trial is funded by MSF; the Research Council of Norway through Norway's Institute of Public Health; the Canadian government through the Public Health Agency of Canada, Canadian Institutes of Health Research, International Development Research Centre and Department of Foreign Affairs, Trade and Development; and WHO, with support from the Wellcome Trust, United Kingdom.

- Read the news release on Ebola vaccine efficacy trial
- Q&A on Ebola phase III vaccine trial in Guinea

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UNMEER [to 7 March 2015]
https://ebolaresponse.un.org/un-mission-ebola-emergency-response-unmeer
:: **From emergency to recovery: EU mobilises efforts to end Ebola and alleviate its impact**
European Commission - Press release
Brussels, 03 March 2015

The "Ebola: from emergency to recovery" conference is taking place in Brussels today under the organisation and patronage of the European Union. While international efforts have reduced the number of Ebola infections in recent months, it is critical to maintain the momentum to prevent a sharp increase in new cases. The conference today aims to sustain the international mobilisation and to plan the next steps in the fight both against the current outbreak and the Ebola virus in general.

The Ebola conference is co-chaired by the European Union, the Presidents of Guinea, Liberia and Sierra Leone, the United Nations, the African Union and the Economic Community of West African States (ECOWAS). It brings together all key international players to prepare the actions needed now to bring the number of Ebola infections down to zero – and the measures to help the affected countries recover from the severe blows that the epidemic has dealt their people and economies…

- EU High Representative, Federica Mogherini, at the Ebola High Level Conference in Brussels
- UNDP Administrator, Helen Clark, "Statement to the media" at the Ebola High Level Conference in Brussels
- UNDP Administrator, Helen Clark, on the Ebola Recovery Assessment at the Ebola High Level Conference in Brussels
- World Bank Group Vice President for Global Practices, Keith Hansen, at the Ebola High Level Conference in Brussels

- UN Special Envoy on Ebola, David Nabarro, Slideshow presentation at the Ebola High Level Conference in Brussels
- UN Special Envoy on Ebola, David Nabarro, Talking points at the Ebola High Level Conference in Brussels
- UNDP Administrator, Helen Clark, opening of the Ebola High Level Conference in Brussels
- Statement of the Co-chairs at the Ebola High Level Conference, Brussels
- WFP Regional Director for West Africa, Denise Brown, at the Ebola High Level Conference in Brussels
- WHO Director-General, Margaret Chan, at the Ebola High Level Conference in Brussels
- UNICEF statement at the Ebola High Level Conference in Brussels

02 Mar 2015
Secretary-General's remarks to the concert "Stop Ebola and Build the Future"

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CDC/MMWR Watch [to 7 March 2015]
http://www.cdc.gov/media/index.html
:: **MMWR Weekly, March 6, 2015 / Vol. 64 / No. 8**
- Update: Influenza Activity — United States, September 28, 2014–February 21, 2015
- Systems for Rapidly Detecting and Treating Persons with Ebola Virus Disease — United States
- Notes from the Field: Increase in Reported Crimean-Congo Hemorrhagic Fever Cases — Country of Georgia, 2014

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Risking Repetition: Are We Ignoring Ebola's Lessons?
International Rescue Committee
New York 02 Mar 2015 -
IRC report outlines significant missteps in the global response to Ebola

Over-focus on treatment, insufficient support for community-led engagement and lack of protection and support for local health workers slowed international response

The International Rescue Committee (IRC) today published a set of recommendations in response to the devastating Ebola outbreak as high-level delegates gather at the European Commission in Brussels to "take stock of the fight against the outbreak, coordinate further action for the total eradication of the disease and discuss the recovery process in the most affected countries."

"The lesson of this crisis is that if you lose the trust of the community then you can't run an effective health system. This is the warning we have to take on board to avoid the risk of repetition," said IRC president and CEO, David Miliband.

The report highlights three key areas that are essential in stopping an outbreak like Ebola in the future:

:: Local Leadership is essential: Quarantines are a salient example of the essential role of local leadership. Enforced quarantines, such as the disastrous closure of the Monrovia neighborhood of West Point, served to fuel the epidemic. In contrast, self-imposed quarantines such as the ones organized in partnership between the IRC and local communities in Lofa Country played a significant role in stopping the epidemic. By and large, local leaders and volunteers were the most effective agents of change.

:: Health Care Workers Must be Paid and Properly Resourced: From Lofa County, Liberia, to Bo District in Sierra Leone the IRC heard directly from doctors and nurses who have not received a regular salary in months. When Ebola struck Liberia, health care workers had just been on strike to protest a lack of wages. With donor support, the governments of both countries must commit to paying their employees a regular and reliable salary. The ongoing response and future recovery must ensure that health care workers receive ongoing training, monitoring, mentorship and supervision.

:: Infection prevention and control across the board: Over five hundred health care workers died fighting Ebola. The IRC recognized that health care workers were putting their lives on the line to fight Ebola and instituted rigorous infection and prevention control trainings across Kenema district. It is imperative that we don't let up. Practices put in place now must be continued and supported. These efforts need to be extended to schools and other public facilities. This is important as a means to restore the public's trust…

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POLIO [to 7 March 2015]
Public Health Emergency of International Concern (PHEIC)

GPEI Update: Polio this week - *As of 4 March 2015*
Global Polio Eradication Initiative
[Editor's Excerpt and text bolding]
Full report: http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx
:: • On the 27 February the Director General accepted the recommendations made by the Emergency Committee of the International Health Regulations concerning the international spread of wild poliovirus. The statement of the recommendations from this fourth meeting can be found here.
• The polio legacy is being demonstrated in action through the work of 26 surveillance experts from the National Polio Surveillance Programme in India who have been deployed to Sierra Leone to support the Ebola outbreak response. Read more.
Selected country report content:
Afghanistan
:: One new case of wild poliovirus type 1 (WPV1) has been reported in the past week in Reg district, Hilmand province. This was the first case reported in 2015, with onset of paralysis on 21 January. The total number of WPV1 cases for 2014 remains 28. Most of the cases from 2014 were linked to cross-border transmission with neighbouring Pakistan.
Pakistan
:: Four new wild poliovirus type 1 (WPV1) cases were reported in the past week. Two cases were reported in Khyber agency, in the Federally Administered Tribal Areas, 1 in Killa Abdullah district of Balochistan province (previously uninfected in 2015) and 1 in Tank district, in Khyber Pakhtunkhwa. The total number of WPV1 cases in 2014 remains 306, and 13 for 2015. The most recent case had onset of paralysis on 3 February in Balochistan.

Statement on the 4th IHR Emergency Committee meeting regarding the international spread of wild poliovirus
WHO statement
27 February 2015

[Editor's text bolding]
The fourth meeting of the Emergency Committee under the International Health Regulations (IHR) (2005) regarding the international spread of wild poliovirus in 2014 - 15 was convened via teleconference by the Director-General on 17 February 2015. The following **IHR States Parties submitted an update on the implementation of the Temporary Recommendations since the Committee last met on 13 November 2014: Cameroon, Equatorial Guinea, Pakistan and the Syrian Arab Republic.**

The Committee noted that the international spread of wild poliovirus has continued with one new exportation from Pakistan into neighbouring Afghanistan documented after 13 November 2014. Although there is seasonal decline in the number of reported cases in Pakistan, transmission is ongoing in each of the four provinces and the Federally Administered Tribal Areas. The Committee assessed the risk of international spread from Pakistan to be sustained. The Committee appreciated that Pakistan has prepared a new robust 'low season' vaccination plan, established national and provincial emergency operations centres, and resumed campaigns in South and North Waziristan. Nonetheless, the principal factors underpinning the international spread of wild poliovirus from Pakistan have not yet changed sufficiently since the date of the third meeting of the Emergency Committee on 13 November 2014.

There has been no other documented international spread of wild poliovirus since March 2014. Although the risk of new international spread from the nine other infected Member States appears to have declined, the possibility of international spread still remains a global threat worsened by the expansion of conflict-affected areas, particularly in the Middle East and Central Africa. Furthermore, countries affected by conflict inevitably experience a decline in health service delivery that leads to deterioration of immunization systems in a number of such at-risk countries.

The Committee assessed that the spread of polio still constitutes a Public Health Emergency of International Concern and recommended the extension of the Temporary Recommendations for a further 3 months.

The committee considered the following factors in reaching this unanimous conclusion:
1. The continued international spread of wild poliovirus through 2014;

2. The risk and consequent costs of failure to eradicate globally one of the world's most serious vaccine preventable diseases;

3. The continued necessity of a coordinated international response to stop the international spread of wild poliovirus and to prevent new spread with the onset of the high transmission season in May/June 2015;

4. **The serious consequences of further international spread for the increasing number of countries in which immunization systems have been disrupted by armed conflict and complex emergencies. Populations in these fragile states are vulnerable to infection and outbreaks of polio which are exceedingly difficult to control;**

5. The importance of a regional approach and cooperation as much international spread of polio occurs over land borders.

The Committee sincerely appreciated the efforts that all countries have made in response to the temporary recommendations and reviewed the progress against the criteria previously established by the Committee for countries to respond to under the IHR. **The Committee remains concerned that implementation of the Temporary Recommendations is incomplete in all affected countries, many of whom are affected by regional conflicts.**

The Committee provided the Director-General with the following advice aimed at reducing the risk of international spread of wild poliovirus, based on an updated risk stratification of the 10 countries that had earlier met the criteria for 'States currently exporting wild poliovirus' or 'States infected with wild poliovirus but not currently exporting '. A third risk category has been added by the Committee for 'States no longer infected by wild poliovirus, but which remain vulnerable to international spread'. The committee also noted the feedback from the four exporting countries that highlighted the challenges of implementing polio eradication measures in situations where there is significant cross-border population movement, often across long borders and common epidemiological blocks. The committee therefore recommended that countries apply a regional approach and develop joint immunisation strategies with neighbouring countries.
[Specific recommendation for States continue…]

Pakistani Officials Issue Arrest Warrants Over Refusals of Polio Vaccine
By ISMAIL KHAN
New York Times, FEB. 27, 2015
PESHAWAR, Pakistan — Determined to curb Pakistan's polio crisis, police officials in the northwestern province of Khyber-Pakhtunkhwa said Friday that they had issued hundreds of arrest warrants for parents for refusing to vaccinate their children.
"We had 13,000 to 16,000 refusal cases," the deputy police commissioner for Peshawar, Riaz Khan Mahsud, said in an interview. "There is total determination on our part. We shall convince parents of the good of vaccinating their children, but if they refuse, we shall detain them. There is no leniency."
The police in other districts of the province also reported issuing warrants, though no official total was released.
"The number keeps fluctuating," said a senior government official, speaking on the condition of anonymity because he was not authorized to brief the news media. "We are applying different laws. You have to resort to coercive measures when persuasion fails."
The official added: "The application of laws is working. Some parents readily agree to vaccinate children to avoid detention. Others take a few days behind the bars to see reason. We take an affidavit from them and let them go if they bring kids for vaccination."…

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WHO & Regionals [to 7 March 2015]
:: **Ten top issues for women's health**
6 March 2015 -- International Women's Day is a day to celebrate women and their achievements. It's also a day to take stock of how women's rights, especially the right to health, are fulfilled in the world. Women still face many health problems. 8 March is an opportunity to

re-commit to addressing issues ranging from cancer to reproductive health, from mental health to HIV. That's why WHO and its partners are developing a new global strategy for women's, children's, and adolescents' health.
Read about the top 10 health issues for women

:: **Global Alert and Response (GAR): Disease Outbreak News (DONs)**
- 6 March 2015 Measles – WHO European Region
- 6 March 2015 Middle East respiratory syndrome coronavirus (MERS-CoV) – Saudi Arabia

:: The **Weekly Epidemiological Record (WER) 6 March 2015**, vol. 90, 10 (pp. 89–96) includes:
- Soil-transmitted helminthiases: number of children treated in 2013
- Ebola virus disease (EVD) in West Africa: an extraordinary epidemic

:: WHO Regional Offices
WHO African Region AFRO
:: WHO strives to provide universal access to immunization in the African Region by 2020
Brazzaville, 6 March 2015 – In efforts to prevent vaccine preventable diseases, health experts concluded a four-day meeting from 2 to 5 March that aimed to ensure that every child in the African Region has access to life-saving vaccines. It is estimated that over three million children under five years of age die each year in the Region and a significant number of these deaths could be prevented by vaccines.
One of the recent developments in the field of immunization is the existence of a Regional Strategic Plan for Immunization 2014–2020, endorsed by Member States during the 64th session of the Regional Committee meeting in November 2014, which provides policy and programmatic guidance to Member States for their immunization programmes. This strategic plan addresses the challenges countries in the WHO African Region and their partners need to overcome to provide universal access to immunization for all eligible populations by 2020…
…The two-day meeting, which was well attended, had immunization partners like the Bill & Melinda Gates Foundation (BMGF), U.S. Centers for Disease Prevention and Control (CDC), USAID, United Nations Children's Fund (UNICEF), Rotary International, Gavi the Vaccine Alliance, Médecins Sans Frontières (MSF), the Network for Education and Support for Immunization (NESI) as well as the different Immunization Advisory Bodies in the Region, namely, the Task Force on Immunization (TFI) in Africa, the African Regional Certification Committee (ARCC), the Measles and Rubella Technical Advisory Group among others present.

:: Sugars contributing to emerging health threats in Africa *- 04 March 2015*

WHO Region of the Americas PAHO
:: PAHO and WHO urge countries to reduce sugar consumption among adults and children (03/04/2015)

:: Congenital anomalies are the second-leading cause of death in children under 5 in the Americas (03/02/2015)

WHO South-East Asia Region SEARO
:: Prevent birth defects, provide care for survivors 03 March 2015

WHO European Region **EURO**
:: European countries to meet in April to review progress on environment and health 05-03-2015

WHO Eastern Mediterranean Region **EMRO**
No new digest content identified.

WHO Western Pacific Region
:: WHO First Embrace campaign to save more than 50 000 newborn babies a year in the Region
MANILA, 5 March 2015 – The World Health Organization (WHO) Region for the Western Pacific launched First Embrace today — a campaign highlighting simple steps that will save more than 50 000 newborn lives, and prevent hundreds of thousands of complications each year from unsafe practices in newborn care in the Region.
- Read the news release

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BMGF – Gates Foundation Watch [to 7 March 2015]
http://www.gatesfoundation.org/Media-Center/Press-Releases
The Bill & Melinda Gates Foundation and CureVac Collaborate to Accelerate the Development of Transformative Vaccine Technology
- *Equity investment of $52 million (€ 46 million) to support construction of a new Good Manufacturing Practice (GMP) production facility*
- *Foundation will separately fund vaccine development programs with the potential to revolutionize the prevention of a wide range of infectious diseases*

SEATTLE and TÜBINGEN, Germany, March 5, 2015 /PRNewswire-USNewswire/ -- The Bill & Melinda Gates Foundation and CureVac today announced that the foundation has made a commitment to invest $52 million (€46 million) in CureVac, a leading clinical-stage biopharmaceutical company specializing in mRNA-based vaccine technologies. As part of the agreement, the foundation will also provide separate funding for several projects to develop prophylactic vaccines based on CureVac's proprietary messenger RNA (mRNA) platform. In addition, CureVac's longstanding investor dievini Hopp BioTech announced a commitment of $24 million (€21 million) of additional equity.

CureVac is pioneering the use of natural and chemically unmodified mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a wide range of diseases. CureVac's novel technology is the broadest and most advanced mRNA therapeutic platform and allows for rapid, low-cost production of multiple drugs and vaccines. Additionally, CureVac's mRNA vaccines are thermostable, which eliminates the demand for cold-chain storage and infrastructure, a major challenge in the vaccine supply of most developing countries.

The investment will support continued development of CureVac's platform technology and the construction of an industrial scale Good Manufacturing Practice (GMP) production facility. As part of this partnership, CureVac and the Gates Foundation will collaborate on the development and production of numerous vaccines against infectious diseases that disproportionately affect people in the world's poorest countries.

"If we can teach the body to create its own natural defenses, we can revolutionize the way we treat and prevent diseases," said Bill Gates, co-chair of the Bill & Melinda Gates Foundation.

"Technologies like mRNA give us confidence to place big bets for the future. We are pleased to partner with CureVac who has been pioneering this technology."

"This collaboration will ensure that one of medicine's most promising new technologies is applied to the challenge of reaching all people with the affordable, life-saving vaccines they need," said Sue Desmond-Hellmann, CEO of the Bill & Melinda Gates Foundation.

The Gates Foundation will provide additional funding – beyond the equity investment – for multiple projects developing vaccines for viral, bacterial and parasitic infectious diseases. The foundation has started work with CureVac on initial projects for diseases such as rotavirus and HIV.

"When I first met CureVac's founders 10 years ago, their vision and technology reminded me of the beginnings of the software industry: mRNA is like software that is able to teach the body to reprogram itself in order to fight cancer and infectious disease. Even today I am not aware of any other biomolecule with such versatile potential," said Dietmar Hopp, through dievini Hopp Biotech, the primary shareholder in CureVac. "I am delighted that Bill Gates and the foundation see it the same way."

Ingmar Hoerr, co-founder and CEO of CureVac, said, "With the Bill & Melinda Gates Foundation we have found another strong and highly committed investor to support us in expanding our mRNA platform at an accelerated pace. We look forward to commencing our mutually beneficial partnership which will allow CureVac to contribute its versatile technology to combat many serious infectious diseases while also benefiting from the foundation's significant network and expertise in the vaccine market. We also very much appreciate the additional commitment from our longstanding investor. We feel very well-positioned to scale up our GMP manufacturing capabilities in order to supply the world markets with our products."

Under the terms of the agreement, any Gates Foundation-funded products will be made available by CureVac at an affordable price in poor countries. CureVac will be able to merchandise each Gates-funded product in developed countries on its own, through licensees or a combination of both. In addition, the new manufacturing facility will have dedicated capacity to focus on products resulting from Gates Foundation-related projects.

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European Medicines Agency Watch [to 7 March 2015]
http://www.ema.europa.eu/ema/
04/03/2015
Use of antimicrobials in animals - public consultations on two guidelines
The guidelines include recommendations that aim to reduce the risk of development of antimicrobial resistance in animals and to prevent transmission of resistance to humans ..

European Vaccine Initiative Watch [to 7 March 2015]
http://www.euvaccine.eu/news-events
:: First SEmalvac annual meeting takes places in May
05 March 2015

The first SEmalvac annual meeting will take place at the Centre National de Recherche et de Formation sur le Paludisme (CNRFP), Burkina Faso on 04 - 07 May 2015. During the meeting, the SEmalvac partners will discuss the status of the phase Ib clinical trial to be conducted in Burkina Faso, and will have the opportunity to visit the clinical trial site in Banfora.

:: IPROVE Vaccine Research Innovation Workshop
05 March 2015
This high-level stakeholder consultation workshop (12 - 13 March in Brussels) organised by the IPROVE FP7 project consortium will feature participation from research, academia, industry, policy bodies, scientific societies and IPROVE project partners' with the goal of identifying key gaps and needs to be addressed jointly and at EU level to bolster vaccine innovation. The workshop will seek to encourage an open and informal exchange of views between all of the experts that have been selected and invited to participate.

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Industry Watch [to 7 March 2015]
:: Pfizer Receives European Approval for New Indication for Prevenar 13 for Prevention of Vaccine-Type Pneumococcal Pneumonia in Adults March 03, 2015

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DCVMN / PhRMA / EFPIA / IFPMA / BIO Watch [to 7 March 2015]
:: Open Letter to G7 Heads of State on Neglected Tropical Diseases
IFPMA - 05 March 2015
…Together, we represent a group of experts, advocates, researchers and implementing partners from public and private sector organizations that share a vision of a world free of neglected tropical diseases (NTDs).1 Our work is underpinned by the landmark 2012 London Declaration on NTDs, which captures our commitment to accelerate progress towards the World Health Organization's (WHO) 2020 control and elimination targets. We are writing to urge you to sustain current funding levels for NTD control and elimination efforts, and implement a collective plan of action to fill the remaining gaps to ensure we reach all people at risk from NTDs…
… Looking forward, the G7 and partners should ensure universal coverage against these diseases, an effort that will lead to measurable progress towards the elimination of extreme poverty; improved maternal and child health outcomes; and enhanced economic growth. Equally important, prioritizing NTDs will set the stage for success in achieving the proposed 2030 sustainable development goals.
To meet this need, the G7 should sustain current funding levels for neglected tropical disease control and elimination efforts, and implement a collective plan of action to fill the remaining gaps:
:: Scale up access to existing treatments through mass drug administration and multisectoral approaches: Currently, just over 40 percent of people at risk of NTDs worldwide are being reached by treatment programs. Therefore, additional investment is essential to ensure coverage of those affected. G7 leaders can advance progress towards their 2008 Hokkaido Toyako commitment by reaching 75% of the people affected by NTDs through cost-effective, integrated approaches like mass drug administration – a bundled packet of NTD treatments that can be delivered through community-based platforms, including schools. In addition, the G7 should invest in multisectoral approaches that integrate NTD control and elimination activities alongside efforts to improve maternal and child health, education, water, sanitation and hygiene, nutrition, reaching more people in need with a greater impact.
:: Invest in new, innovative technologies and approaches: While we must continue to utilize these cost-effective, high-impact treatments, some NTDs require increased investment in new

innovative technologies including drugs, diagnostics, vaccines and pesticides. One possible avenue for research and development support is through product development partnerships that can facilitate exchange of expertise and scientific knowledge to develop products for diseases that disproportionally affect the most vulnerable populations…

::::::

UNICEF Watch [to 7 March 2015]
No new digest content identified.

GAVI [to 7 March 2015]
http://www.gavialliance.org/library/news/press-releases/
No new digest content identified.

Global Fund [to 7 March 2015]
http://www.theglobalfund.org/en/mediacenter/newsreleases/
No new digest content identified.

Sabin Vaccine Institute Watch [to 7 March 2015]
http://www.sabin.org/updates/pressreleases
No new digest content identified.

IVI Watch [to 7 March 2015]
http://www.ivi.org/web/www/home
No new digest content identified.

PATH Watch [to 7 March 2015]
http://www.path.org/news/index.php
No new digest content identified.

NIH Watch [to 7 March 2015]
http://www.nih.gov/news/index.html
No new digest content identified.

FDA Watch [to 7 March 2015]
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
No new digest content identified.

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

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

Development of Dengue Vaccines - Status Review and Future Considerations

REPORT OF THE ASIA-PACIFIC DENGUE PREVENTION BOARD MEETING
Seoul, Korea November 21 – 22, 2014 :: 38 pages
Pdf:
http://www.denguevaccines.org/sites/default/files/APDPB%202014%20report_final_3615.pdf
Overview

In November of 2014, DVI held a two-day meeting to discuss the status of a dengue vaccine and exchange views on its licensure and introduction. Members of the Asia-Pacific Dengue Prevention Board (DPB), modelers of the impact of vaccination on dengue, public health specialists and dengue vaccine candidate representatives contributed to these conversations.

The Board convened at a critical time -- 2014 marked a milestone for the fight against dengue fever, with the first ever successful completion of Phase III clinical trials on a dengue vaccine candidate (CYD-TDV). These trials demonstrated that a vaccine that can prevent dengue cases is feasible, showing both safety and overall moderate efficacy, especially against the most severe outcomes of dengue infection, in both Asia and the Americas. At the same time, other vaccine candidates continued to progress in clinical development throughout the year, as did modeling of the impact of vaccination on dengue incidence.

These updates, and the new information they contribute to the field of dengue research, warrant a reassessment of the potential implications of dengue vaccine introduction in endemic countries. DVI will continue to support countries' efforts to successfully plan for the introduction of dengue vaccines through evidenced-based research to help inform decision-making. One of these efforts is the upcoming Americas DPB meeting in March 16 and 17 in Bogota, Colombia. DVI looks forward to what is sure to be another productive exchange -- one that can complement the conversations had in Seoul and raise points for further analysis, discussion, and knowledge sharing.

Professor Wilder-Smith Named New Senior Advisor to DVI

WASHINGTON, DC – March 6, 2015 – The members of the Dengue Vaccine Initiative (DVI) consortium, the International Vaccine Institute, the Johns Hopkins University International Vaccine Access Center, the Sabin Vaccine Institute and the World Health Organization, are delighted to announce the appointment of Professor Annelies Wilder-Smith as Senior Advisor to the DVI, effective immediately.

"We are extraordinarily pleased that Professor Wilder-Smith has joined us to provide guidance to DVI and ensure a smooth transition until a new full-time Director joins the Initiative. Her leadership in the research of dengue control and surveillance strategies will contribute to our efforts of laying the groundwork for the introduction of a dengue vaccine" said Dr. Jerome Kim, International Vaccine Institute Director General…

Financing Investments in Young Children Globally

Summary of a Joint Workshop by the Institute of Medicine, National Research Council, and The Centre for Early Childhood Education and Development, Ambedkar University, Delhi (2015)
March 6, 2015 :: 108 pages ISBN: 978-0-309-31610-1
Pdf dpwmload:
https://www.nap.edu/login.php?record_id=18993&page=http%3A%2F%2Fwww.nap.edu%2Fdownload.php%3Frecord_id%3D18993
Overview

On August 26–27, 2014, the Forum on Investing in Young Children Globally hosted its second workshop, in New Delhi, India. The forum's first workshop, titled "The Cost of Inaction," was held in Washington, DC, in April 2014 and focused on the science of promoting optimal development through investing in young children and the potential economic consequences of inaction. This second workshop, on financing investments for young children, built on the first workshop and brought together stakeholders from such disciplines as social protection, nutrition, education, health, finance, economics, and law and included practitioners, advocates, researchers, and policy makers.

FORUM ON INVESTING IN YOUNG CHILDREN GLOBALLY - OVERVIEW

In January 2014, the Board on Children, Youth, and Families of the Institute of Medicine (IOM) and the National Research Council (NRC), in collaboration with the IOM Board on Global Health, launched the Forum on Investing in Young Children Globally. At this meeting, the participants agreed to focus on creating and sustaining, over 3 years, an evidence-driven community of stakeholders that aims to explore existing, new, and innovative science and research from around the world and translate this evidence into sound and strategic investments in policies and practices that will make a difference in the lives of children and their caregivers.

Forum activities will highlight the science and economics of integrated investments in young children living in low-resourced regions of the world across the areas of health, nutrition, education, and social protection.

As a result, the forum will explore a holistic view of children and caregivers by integrating analyses and disciplines that span from neurons to neighborhoods and discuss the science from the microbiome to culture. Moreover, the forum will support an integrative vision to strengthen human capital. This work will be done through the forum and will engage in a series of stakeholder consultative sessions or public workshops, each focusing on specific aspects of science integration, bridging equity gaps, and implementing and scaling evidence-informed efforts.

A set of forum goals includes supporting the development of integrated science on children's health, nutrition, education, and social protection and working with policy makers, practitioners, and researchers to raise awareness of integrated approaches to improve the lives of children and their caregivers. Forum objectives to meet these goals are as follows:

1. To shape a global vision of healthy child development across cultures and contexts, extending from preconception through at least age eight, and across currently siloed areas of health, nutrition, education, and social protection.

2. To identify opportunities for intersectoral coordination among researchers, policy makers, implementers, practitioners, and advocates to improve quality practices in public and private settings and bring these practices to scale, in the context of the economics of strategic, integrated investing in young children.

3. To inform ongoing conversations and activities of groups working on issues related to young children globally, such as the sustainable development goals and indicators being developed.

4. To identify current models of program and policy financing across health, education, nutrition, and social protection within the framework of reproductive, maternal, newborn, and child health that aim to improve children's developmental potential.

This information could be used to illuminate opportunities for new financing structures and forms of investments that may be more effective in improving child outcomes and potentially drive economic development.

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
Volume 15, Issue 2, 2015
http://www.tandfonline.com/toc/uajb20/current
[Reviewed earlier]

American Journal of Infection Control
March 2015 Volume 43, Issue 3, p199-312
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
March 2015 Volume 48, Issue 3, p241-364, e1-e4
http://www.ajpmonline.org/current
[Reviewed earlier]

American Journal of Public Health
Volume 105, Issue 3 (March 2015)
http://ajph.aphapublications.org/toc/ajph/current
[Reviewed earlier]

American Journal of Tropical Medicine and Hygiene
March 2015; 92 (3)

http://www.ajtmh.org/content/current
[New issue; No relevant content]

Annals of Internal Medicine
3 March 2015, Vol. 162. No. 5
http://annals.org/issue.aspx
[New issue; No relevant content]

BMC Health Services Research
http://www.biomedcentral.com/bmchealthservres/content
(Accessed 7 March 2015)
[No new relevant content]

BMC Infectious Diseases
http://www.biomedcentral.com/bmcinfectdis/content
(Accessed 7 March 2015)
[No new relevant content]

BMC Medical Ethics
(Accessed 7 March 2015)
http://www.biomedcentral.com/bmcmedethics/content
[No new relevant content]

BMC Public Health
(Accessed 7 March 2015)
http://www.biomedcentral.com/bmcpublichealth/content
Research article
The HIV epidemic and sexual and reproductive health policy integration: views of South African policymakers
Diane Cooper, Joanne E Mantell, Jennifer Moodley, Sumaya Mall BMC Public Health 2015, 15:217 (4 March 2015)
*Abstract (*provisional)
Background
Integration of sexual and reproductive health (SRH) and HIV policies and services delivered by the same provider is prioritised worldwide, especially in sub-Saharan Africa where HIV prevalence is highest. South Africa has the largest antiretroviral treatment (ART) programme in the world, with an estimated 2.7 million people on ART, elevating South Africa's prominence as a global leader in HIV treatment. In 2011, the Southern African HIV Clinicians Society published safer conception guidelines for people living with HIV (PLWH) and in 2013, the South African government published contraceptive guidelines highlighting the importance of SRH and fertility planning services for people living with HIV. Addressing unintended pregnancies, safer conception and maternal health issues is crucial for improving PLWH's SRH and combatting the global HIV epidemic. This paper explores South African policymakers' perspectives on public

sector SRH-HIV policy integration, with a special focus on the need for national and regional policies on safer conception for PLWH and contraceptive guidelines implementation.
Methods
It draws on 42 in-depth interviews with national, provincial and civil society policymakers conducted between 2008–2009 and 2011–2012, as the number of people on ART escalated. Interviews focused on three key domains: opinions on PLWH's childbearing; the status of SRH-HIV integration policies and services; and thoughts and suggestions on SRH-HIV integration within the restructuring of South African primary care services. Data were coded and analysed according to themes.
Results
Participants supported SRH-HIV integrated policy and services. However, integration challenges identified included a lack of policy and guidelines, inadequately trained providers, vertical programming, provider work overload, and a weak health system. Participants acknowledged that SRH-HIV integration policies, particularly for safer conception, contraception and cervical cancer, had been neglected. Policymakers supported public sector adoption of safer conception policy and services. Participants interviewed after expanded ART were more positive about safer conception policies for PLWH than participants interviewed earlier.
Conclusion
The past decade's HIV policy changes have increased opportunities for SRH –HIV integration. The findings provide important insights for international, regional and national SRH-HIV policy and service integration initiatives.

Debate

A critical review of population health literacy assessment

Diana Guzys[1]*, Amanda Kenny[1], Virginia Dickson-Swift[1] and Guinever Threlkeld[2]

Abstract
Background
Defining health literacy from a public health perspective places greater emphasis on the knowledge and skills required to prevent disease and for promoting health in everyday life. Addressing health literacy at the community level provides great potential for improving health knowledge, skills and behaviours resulting in better health outcomes. Yet there is a notable absence of discussion in the literature of what a health literate population looks like, or how this is best assessed.
Discussion
The emphasis in assessing health literacy has predominantly focused on the functional health literacy of individuals in clinical settings. This review examines currently available health literacy assessment tools to identify how well suited they are in addressing health literacy beyond clinical care settings and beyond the individual. Although public health literature appears to place greater emphasis on conceptualizing critical health literacy, the focus continues to remain on assessing individuals, rather than on health literacy within the context of families, communities and population groups. When a population approach is adopted, an aggregate of individual health literacy assessment is generally used. Aggregation of individual health literacy fails to capture the dynamic and often synergistic relationships within communities, and fails to reflect societal influences on health knowledge, beliefs and behaviours.
We hypothesise that a different assessment framework is required to adequately address the complexities of community health literacy. We assert that a public health approach, founded on health promotion theories provides a useful scaffold to assess the critical health literacy of population groups. It is proposed that inclusion of community members in the research process is a necessary requirement to coproduce such an appropriate assessment framework.

Summary
We contend that health literacy assessment and potential interventions need to shift to promoting the knowledge and skills essential for critical health literacy at a societal level. The challenge for researchers is to negotiate the myriad of complexities associated with each concept and component required for this task.

BMC Research Notes
(Accessed 7 March 2015)
http://www.biomedcentral.com/bmcresnotes/content
[No new relevant content]

British Medical Journal
07 March 2015(vol 350, issue 7998)
http://www.bmj.com/content/350/7998
Editorials
The evidence base for new drugs
BMJ 2015; 350 doi: http://dx.doi.org/10.1136/bmj.h952 (Published 02 March 2015) Cite this as: BMJ 2015;350:h952
Peter Doshi, associate editor1,
Tom Jefferson, reviewer2
Author affiliations
New legislation in Germany provides another piece of a complex puzzle

Marketing campaigns cast new drugs as "must haves." In reality, the public evidence base for new drugs often leaves more questions than answers.1 2 While marketing authorization indicates that regulators judged the risk-benefit profile to be favorable, product labels rarely list and quantify these benefits and harms. Publications of premarketing trials might fill in some gaps, but readers beware: not all trials are published and those that are may be inaccurately or incompletely reported.3 4

Data transparency in clinical trials has emerged as a way to tackle the reporting biases that affect literature, enabling independent scrutiny of trials.5 But it is not enough. Even with open data we rarely know how new drugs compare with existing options or whether they improve patient centered outcomes. An analysis published in this issue (doi:10.1136/bmj.h796) suggests that new legislation in Germany may provide another piece of the puzzle.6

The German act on the reform of the market for medicinal products (AMNOG) was introduced in 2011 to inform drug pricing for all new drugs. To control costs, sponsors must submit a standardized dossier including evidence of the drug's added benefit over already available drugs. This dossier is then reviewed by scientists, usually at the Institute for Quality and Efficiency in Health Care (IQWiG), who produce an assessment report.

Editorials
Health literacy: towards system level solutions
BMJ 2015; 350 doi: http://dx.doi.org/10.1136/bmj.h1026 (Published 24 February 2015) Cite this as: BMJ 2015;350:h1026
Trisha Greenhalgh, professor of primary care health sciences
Author affiliations
A new World Health Organization toolkit aimed at low and middle income countries could help reduce health inequalities in the rest of the world too

a new resource aimed at low and middle income countries, the World Health Organization has redefined health literacy as "the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health."1

Low health literacy is associated with poor engagement with health services, health knowledge, concordance with prescribed medication, self management of illness, markers of disease progression, overall health status, and survival. It is also associated with high rates of hospital admission and use of emergency care.2 3 4 5 6 7

Low health literacy is more common in low income and minority ethnic groups, immigrants, people without full citizenship, those with fewer years of education, and older people; it is especially common in people who fall into several of these risk groups.8 9 10 11 People with low health literacy may feel ashamed and try to conceal it from professional carers and family members.12 Differences in health literacy explain a substantial proportion of inequity in the uptake and use …

Research

The impact of providing rapid diagnostic malaria tests on fever management in the private retail sector in Ghana: a cluster randomized trial

BMJ 2015; 350 :h1019 (Published 04 March 2015)

PDF

Open Access

Abstract

Objective

To examine the impact of providing rapid diagnostic tests for malaria on fever management in private drug retail shops where most poor rural people with fever present, with the aim of reducing current massive overdiagnosis and overtreatment of malaria.

Design

Cluster randomized trial of 24 clusters of shops.

Setting

Dangme West, a poor rural district of Ghana.

Participants

Shops and their clients, both adults and children.

Interventions

Providing rapid diagnostic tests with realistic training.

Main outcome measures

The primary outcome was the proportion of clients testing negative for malaria by a double-read research blood slide who received an artemisinin combination therapy or other antimalarial. Secondary outcomes were use of antibiotics and antipyretics, and safety.

Results Of 4603 clients, 3424 (74.4%) tested negative by double-read research slides. The proportion of slide-negative clients who received any antimalarial was 590/1854 (32%) in the intervention arm and 1378/1570 (88%) in the control arm (adjusted risk ratio 0.41 (95% CI 0.29 to 0.58), P<0.0001). Treatment was in high agreement with rapid diagnostic test result. Of those who were slide-positive, 690/787 (87.8%) in the intervention arm and 347/392 (88.5%) in the control arm received an artemisinin combination therapy (adjusted risk ratio 0.96 (0.84 to 1.09)). There was no evidence of antibiotics being substituted for antimalarials. Overall, 1954/2641 (74%) clients in the intervention arm and 539/1962 (27%) in the control arm received appropriate treatment (adjusted risk ratio 2.39 (1.69 to 3.39), P<0.0001). No safety concerns were identified.

Conclusions

Most patients with fever in Africa present to the private sector. In this trial, providing rapid diagnostic tests for malaria in the private drug retail sector significantly reduced dispensing of antimalarials to patients without malaria, did not reduce prescribing of antimalarials to true malaria cases, and appeared safe. Rapid diagnostic tests should be considered for the informal private drug retail sector.

Registration Clinicaltrials.gov NCT01907672

Information on new drugs at market entry: retrospective analysis of health technology assessment reports versus regulatory reports, journal publications, and registry reports

BMJ 2015; 350 :h796 (Published 26 February 2015)

PDF

Open Access

Abstract

Background

When a new drug becomes available, patients and doctors require information on its benefits and harms. In 2011, Germany introduced the early benefit assessment of new drugs through the act on the reform of the market for medicinal products (AMNOG). At market entry, the pharmaceutical company responsible must submit a standardised dossier containing all available evidence of the drug's added benefit over an appropriate comparator treatment. The added benefit is mainly determined using patient relevant outcomes. The "dossier assessment" is generally performed by the Institute for Quality and Efficiency in Health Care (IQWiG) and then published online. It contains all relevant study information, including data from unpublished clinical study reports contained in the dossiers. The dossier assessment refers to the patient population for which the new drug is approved according to the summary of product characteristics. This patient population may comprise either the total populations investigated in the studies submitted to regulatory authorities in the drug approval process, or the specific subpopulations defined in the summary of product characteristics ("approved subpopulations").

Objective

To determine the information gain from AMNOG documents compared with non-AMNOG documents for methods and results of studies available at market entry of new drugs. AMNOG documents comprise dossier assessments done by IQWiG and publicly available modules of company dossiers; non-AMNOG documents comprise conventional, publicly available sources—that is, European public assessment reports, journal publications, and registry reports. The analysis focused on the approved patient populations.

Design

Retrospective analysis.

Data sources

All dossier assessments conducted by IQWiG between 1 January 2011 and 28 February 2013 in which the dossiers contained suitable studies allowing for a full early benefit assessment. We also considered all European public assessment reports, journal publications, and registry reports referring to these studies and included in the dossiers.

Data analysis

We assessed reporting quality for each study and each available document for eight methods and 11 results items (three baseline characteristics and eight patient relevant outcomes), and dichotomised them as "completely reported" or "incompletely reported (including items not reported at all)." For each document type we calculated the proportion of items with complete reporting for methods and results, for each item and overall, and compared the findings.

Results

15 out of 27 dossiers were eligible for inclusion and contained 22 studies. The 15 dossier assessments contained 28 individual assessments of 15 total study populations and 13 approved subpopulations. European public assessment reports were available for all drugs. Journal publications were available for 14 out of 15 drugs and 21 out of 22 studies. A registry report in ClinicalTrials.gov was available for all drugs and studies; however, only 11 contained results. In the analysis of total study populations, the AMNOG documents reached the highest grade of completeness, with about 90% of methods and results items completely reported. In non-AMNOG documents, the rate was 75% for methods and 52% for results items; journal publications achieved the best rates, followed by European public assessment reports and registry reports. The analysis of approved subpopulations showed poorer complete reporting of results items, particularly in non-AMNOG documents (non-AMNOG versus AMNOG: 11% v 71% for overall results items and 5% v 70% for patient relevant outcomes). The main limitation of our analysis is the small sample size.
Conclusion
Conventional, publicly available sources provide insufficient information on new drugs, especially on patient relevant outcomes in approved subpopulations. This type of information is largely available in AMNOG documents, albeit only partly in English. The AMNOG approach could be used internationally to develop a comprehensive publication model for clinical studies and thus represents a key open access measure.

Bulletin of the World Health Organization
Volume 93, Number 3, March 2015, 133-208
http://www.who.int/bulletin/volumes/93/3/en/
[Reviewed earlier]

Clinical Infectious Diseases (CID)
Volume 60 Issue 6 March 15, 2015
http://cid.oxfordjournals.org/content/current
Editor's choice: Long-term Persistence of Zoster Vaccine Efficacy
Clin Infect Dis. (2015) 60 (6): 900-909 doi:10.1093/cid/ciu918
Vicki A. Morrison, Gary R. Johnson, Kenneth E. Schmader, Myron J. Levin, Jane H. Zhang, David J. Looney, Robert Betts, Larry Gelb, John C. Guatelli, Ruth Harbecke, Connie Pachucki, Susan Keay, Barbara Menzies, Marie R. Griffin, Carol A. Kauffman, Adriana Marques, John Toney, Kathy Boardman, Shu-Chih Su, Xiaoming Li, Ivan S. F. Chan, Janie Parrino, Paula Annunziato, and Michael N. Oxmanfor the Shingles Prevention Study Group
Free Full Text (HTML)
Free Full Text (PDF)
Abstract
Background.
The Shingles Prevention Study (SPS) demonstrated zoster vaccine efficacy through 4 years postvaccination. A Short-Term Persistence Substudy (STPS) demonstrated persistence of vaccine efficacy for at least 5 years. A Long-Term Persistence Substudy (LTPS) was undertaken to further assess vaccine efficacy in SPS vaccine recipients followed for up to 11 years postvaccination. Study outcomes were assessed for the entire LTPS period and for each year from 7 to 11 years postvaccination.
Methods.

Surveillance, case determination, and follow-up were comparable to those in SPS and STPS. Because SPS placebo recipients were offered zoster vaccine before the LTPS began, there were no unvaccinated controls. Instead, SPS and STPS placebo results were used to model reference placebo groups.
Results.
The LTPS enrolled 6867 SPS vaccine recipients. Compared to SPS, estimated vaccine efficacy in LTPS decreased from 61.1% to 37.3% for the herpes zoster (HZ) burden of illness (BOI), from 66.5% to 35.4% for incidence of postherpetic neuralgia, and from 51.3% to 21.1% for incidence of HZ, and declined for all 3 outcome measures from 7 through 11 years postvaccination. Vaccine efficacy for the HZ BOI was significantly greater than zero through year 10 postvaccination, whereas vaccine efficacy for incidence of HZ was significantly greater than zero only through year 8.
Conclusions.
Estimates of vaccine efficacy decreased over time in the LTPS population compared with modeled control estimates. Statistically significant vaccine efficacy for HZ BOI persisted into year 10 postvaccination, whereas statistically significant vaccine efficacy for incidence of HZ persisted only through year 8.

Editor's choice: Editorial Commentary: Waning Efficacy of the Herpes Zoster Vaccine

Richard J. Whitley
Clin Infect Dis. (2015) 60 (6): 910-911 doi:10.1093/cid/ciu922
Extract
In this issue of Clinical Infectious Diseases, Morrison and colleagues report the waning efficacy of the herpes zoster (HZ) vaccine with long-term follow-up [1]. This report is the third that defines efficacy of vaccination. The first clinical trial reported the unequivocal efficacy of vaccination of individuals >60 years of age for burden of illness (BOI), incidence of postherpetic neuralgia (PHN), and incidence of HZ [2]. These 3 endpoints were assessed through 4 years postvaccination. A subsequent follow-up study through 7 years of postvaccination evaluation noted persistence of efficacy with slightly lower evidence of benefit than the original clinical trial [3], albeit not statistically significant. With the report of Morrison et al, we are able to reasonably estimate the efficacy of vaccination through year 10, and to a significantly lesser extent year 11…

Vaccines Against Malaria

Amed Ouattara and Matthew B. Laurens
Clin Infect Dis. (2015) 60 (6): 930-936 doi:10.1093/cid/ciu954
Abstract
Despite global efforts to control malaria, the illness remains a significant public health threat. Currently, there is no licensed vaccine against malaria, but an efficacious vaccine would represent an important public health tool for successful malaria elimination. Malaria vaccine development continues to be hindered by a poor understanding of antimalarial immunity, a lack of an immune correlate of protection, and the genetic diversity of malaria parasites. Current vaccine development efforts largely target Plasmodium falciparum parasites in the pre-erythrocytic and erythrocytic stages, with some research on transmission-blocking vaccines against asexual stages and vaccines against pregnancy-associated malaria. The leading pre-erythrocytic vaccine candidate is RTS,S, and early results of ongoing Phase 3 testing show overall efficacy of 46% against clinical malaria. The next steps for malaria vaccine development will focus on the design of a product that is efficacious against the highly diverse strains of malaria and the identification of a correlate of protection against disease.

Clinical Therapeutics
February 2015 Volume 37, Issue 2, p243-480
http://www.clinicaltherapeutics.com/current
[Reviewed earlier]

Complexity
January/February 2015 Volume 20, Issue 3 Pages fmi–fmi, 1–92
http://onlinelibrary.wiley.com/doi/10.1002/cplx.v20.3/issuetoc
[Reviewed earlier]

Conflict and Health
[Accessed 7 March 2015]
http://www.conflictandhealth.com/
[No new relevant content]

Contemporary Clinical Trials
Volume 41, In Progress (March 2015)
[Reviewed earlier]

Cost Effectiveness and Resource Allocation
(Accessed 7 March 2015)
http://www.resource-allocation.com/
[No new relevant content]

Current Opinion in Infectious Diseases
April 2015 - Volume 28 - Issue 2 pp: v-v,117-198
http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx
[New issue; No relevant content]

Developing World Bioethics
April 2015 Volume 15, Issue 1 Pages ii–iii, 1–57
http://onlinelibrary.wiley.com/doi/10.1111/dewb.2015.15.issue-1/issuetoc
EDITORIAL
Empirical Research and Bioethics
Debora Diniz
Article first published online: 3 MAR 2015
DOI: 10.1111/dewb.12078
Extract
What counts as empirical evidence in bioethics? Differently from epidemiology or social sciences, bioethics is more argumentative than demonstrative, more normative than explanatory. Saying that, I am suggesting some parameters for the field: we need strong

concepts, yet pieces of data. My provocative argument is that we should not import the epistemic criteria of what counts as data from epidemiology or social sciences to evaluate a contribution as relevant to bioethics. An ethical argument is more important than a long deep description of data…

ARTICLE

Cultural Conundrums: The Ethics of Epidemiology and the Problems of Population in Implementing Pre-Exposure Prophylaxis

Kirk Fiereck*

Article first published online: 23 DEC 2013
DOI: 10.1111/dewb.12034

Abstract

The impending implementation of pre-exposure prophylaxis (PrEP) has prompted complicated bioethical and public health ethics concerns regarding the moral distribution of antiretroviral medications (ARVs) to ostensibly healthy populations as a form of HIV prevention when millions of HIV-positive people still lack access to ARVs globally. This manuscript argues that these questions are, in part, concerns over the ethics of the knowledge production practices of epidemiology. Questions of distribution, and their attendant cost-benefit calculations, will rely on a number of presupposed, and therefore, normatively cultural assumptions within the science of epidemiology specifically regarding the ability of epidemiologic surveillance to produce accurate maps of HIV throughout national populations. Specifically, ethical questions around PrEP will focus on who should receive ARVs given the fact that global demand will far exceed supply. Given that sexual transmission is one of the main modes of HIV transmission, these questions of 'who' are inextricably linked to knowledge about sexual personhood. As a result, the ethics of epidemiology, and how the epidemiology of HIV in particular conceives, classifies and constructs sexual populations will become a critical point of reflection and contestation for bioethicists, health activists, physicians, nurses, and researchers in the multi-disciplinary field of global health. This paper examines how cultural conundrums within the fields of bioethics and public health ethics are directly implicated within the ethics of PrEP, by analyzing the problems of population inaugurated by the construction of the men who have sex with men (MSM) epidemiologic category in the specific national context of South Africa.

ARTICLE

Not Fit for Purpose: The Ethical Guidelines of the Indian Council of Medical Research

Priya Satalkar* and David Shaw

Article first published online: 8 NOV 2013
DOI: 10.1111/dewb.12036

Abstract

In 2006, the Indian Council of Medical Research (ICMR) published its 'Ethical guidelines for Biomedical Research on human participants'. The intention was to translate international ethical standards into locally and culturally appropriate norms and values to help biomedical researchers in India to conduct ethical research and thereby safeguard the interest of human subjects. Unfortunately, it is apparent that the guideline is not fit for purpose. In addition to problems with the structure and clarity of the guidelines, there are several serious omissions and contradictions in the recommendations. In this paper, we take a close look at the two key chapters and highlight some of the striking flaws in this important document. We conclude that ethics committees and national authorities should not lose sight of international ethical standards while incorporating local reality and cultural and social values, as focusing too much on the local context could compromise the safety of human subjects in biomedical research, particularly in India.

Development in Practice
Volume 25, Issue 1, 2015
http://www.tandfonline.com/toc/cdip20/current
[Reviewed earlier]

Emerging Infectious Diseases
Volume 21, Number 3—March 2015
http://wwwnc.cdc.gov/eid/
[Reviewed earlier]

Epidemics
Volume 11, In Progress (June 2015)
http://www.sciencedirect.com/science/journal/17554365
[Reviewed earlier]

Epidemiology and Infection
Volume 143 - Issue 03 - February 2015
http://journals.cambridge.org/action/displayIssue?jid=HYG&tab=currentissue
[Reviewed earlier]

The European Journal of Public Health
Volume 25, Issue 1, 01 February 2015
http://eurpub.oxfordjournals.org/content/25/suppl_1
Theme: Unwarranted variations in health care performance across Europe: Lessons from the ECHO Project
[Reviewed earlier]

Eurosurveillance
Volume 20, Issue 9, 05 March 2015
http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678
Rapid communications
An ongoing measles outbreak in the Federation of Bosnia and Herzegovina, 2014 to 2015
by M Hukic, J Ravlija, S Karakas, M Mulaomerovic, A Dedeic Ljubovic, I Salimović-Besic, M Seremet, S Ahmetagic, A Comor, E Feric
Research articles
Characteristics and practices of National Immunisation Technical Advisory Groups in Europe and potential for collaboration, April 2014
by A Takla, O Wichmann, P Carrillo-Santisteve, S Cotter, D Lévy-Bruhl, I Paradowska-Stankiewicz, P Valentiner-Branth , F D'Ancona, the VENICE III NITAG Survey Group

Global Health: Science and Practice (GHSP)
March 2015 | Volume 3 | Issue 1
http://www.ghspjournal.org/content/current
EDITORIALS
ARVs: The Next Generation. Going Boldly Together to New Frontiers of HIV Treatment
New antiretrovirals (ARVs), particularly the potentially "game-changing" ARV dolutegravir, offer major potential to meet the compelling need for simpler and better HIV treatment for tens of millions of people in the coming decade. Advantages include substantially lower manufacturing cost, fewer side effects, and less risk of resistance. But key obstacles must be addressed in order to develop and introduce new ARVs in specific combinations optimized for the needs of low- and middle-income countries. Strong leadership will be essential from the global health community to nurture more focused collaboration between the private and public sectors.
Matthew Barnhart, James D Shelton
Glob Health Sci Pract 2015;3(1):1-11. First published online January 27, 2015.
http://dx.doi.org/10.9745/GHSP-D-14-00243
Stunning Popularity of LARCs With Good Access and Quality: A Major Opportunity to Meet Family Planning Needs
Given true choice, a very high proportion of women, perhaps most, would select one of the long-acting reversible contraceptives (LARCs)—implants or IUDs—for contraception. If implemented on a wide scale, it would not only drastically alter the current method mix but also serve client needs much better and prevent unintended pregnancy more successfully.
Glob Health Sci Pract 2015;3(1):12-13. First published online February 25, 2015.
http://dx.doi.org/10.9745/GHSP-D-15-00044
ORIGINAL ARTICLES
Delivering High-Quality Family Planning Services in Crisis-Affected Settings I: Program Implementation
Dora Ward Curry, Jesse Rattan, Jean Jose Nzau, Kamlesh Giri
Glob Health Sci Pract 2015;3(1):14-24. First published online February 4, 2015.
http://dx.doi.org/10.9745/GHSP-D-14-00164
ABSTRACT
In 2012, about 43 million women of reproductive age experienced the effects of conflict. Provision of basic sexual and reproductive health services, including family planning, is a recognized right and need of refugees and internally displaced people, but funding and services for family planning have been inadequate. This article describes lessons learned during the first 2.5 years of implementing the ongoing Supporting Access to Family Planning and Post-Abortion Care in Emergencies (SAFPAC) initiative, led by CARE, which supports government health systems to deliver family planning services in 5 crisis-affected settings (Chad, Democratic Republic of the Congo, Djibouti, Mali, and Pakistan). SAFPAC's strategy focuses on 4 broad interventions drawn from public health best practices in more stable settings: competency-based training for providers, improved supply chain management, regular supervision, and community mobilization to influence attitudes and norms related to family planning. Between July 2011 and December 2013, the initiative reached 52,616 new users of modern contraceptive methods across the 5 countries (catchment population of 698,053 women of reproductive age), 61% of whom chose long-acting methods of implants or intrauterine devices. Prudent use of data to inform decision making has been an underpinning to the project's approach. A key approach to ensuring sustained ability to train and supervise new providers has been to build

capacity in clinical skills training and supervision by establishing in-country training centers. In addition, monthly supervision using simple checklists has improved program and service quality, particularly with infection prevention procedures and stock management. We have generally instituted a "pull" system to manage commodities and other supplies, whereby health facilities place resupply orders as needed based on actual consumption patterns and stock-alert thresholds. Finally, reaching the community with mobilization efforts appropriate to the cultural context has been integral to meeting unmet family planning needs rapidly in these crisis-affected settings. Despite the constraints in crisis-affected countries, such as travel difficulties due to security issues, in our experience, we have been able to extend access to a range of contraceptive methods, including long-acting reversible contraceptives, in such settings using best practice approaches established in more stable environments.

Delivering High-Quality Family Planning Services in Crisis-Affected Settings II: Results

Dora Ward Curry, Jesse Rattan, Shuyuan Huang,
Elizabeth Noznesky

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http://dx.doi.org/10.9745/GHSP-D-14-00112

ABSTRACT

An estimated 43 million women of reproductive age experienced the effects of conflict in 2012. Already vulnerable from the insecurity of the emergency, women must also face the continuing risk of unwanted pregnancy but often are unable to obtain family planning services. The ongoing Supporting Access to Family Planning and Post-Abortion Care (SAFPAC) initiative, led by CARE, has provided contraceptives, including long-acting reversible contraceptives (LARCs), to refugees, internally displaced persons, and conflict-affected resident populations in Chad, the Democratic Republic of the Congo (DRC), Djibouti, Mali, and Pakistan. The project works through the Ministry of Health in 4 key areas: (1) competency-based training, (2) supply chain management, (3) systematic supervision, and (4) community mobilization to raise awareness and shift norms related to family planning. This article presents data on program results from July 2011 to December 2013 from the 5 countries. Project staff summarized monthly data from client registers using hard-copy forms and recorded the data electronically in Microsoft Excel for compilation and analysis. The initiative reached 52,616 new users of modern contraceptive methods across the 5 countries, ranging from 575 in Djibouti to 21,191 in Chad. LARCs have predominated overall, representing 61% of new modern method users. The percentage of new users choosing LARCs varied by country: 78% in the DRC, 72% in Chad, and 51% in Mali, but only 29% in Pakistan. In Djibouti, those methods were not offered in the country through SAFPAC during the period discussed here. In Chad, the DRC, and Mali, implants have been the most popular LARC method, while in Pakistan the IUD has been more popular. Use of IUDs, however, has comprised a larger share of the method mix over time in all 4 of these countries. These results to date suggest that it is feasible to work with the public sector in fragile, crisis-affected states to deliver a wide range of quality family planning services, to do so rapidly, and to see a dramatic increase in the percentage of users choosing long-acting reversible methods.

Successful Proof of Concept of Family Planning and Immunization Integration in Liberia

Chelsea M Coopera⇑, Rebecca Fieldsb, Corinne I Mazzeoc, Nyapu Taylord, Anne Pfitzera, Mary Momolue, Cuallau Jabbeh-Howee

ABSTRACT

Globally, unmet need for postpartum family planning remains high, while immunization services are among the most wide-reaching and equitable interventions. Given overlapping time frames,

integrating these services provides an opportunity to leverage existing health visits to offer women more comprehensive services. From March through November 2012, Liberia's government, with support from the Maternal and Child Health Integrated Program (MCHIP), piloted an integrated family planning and immunization model at 10 health facilities in Bong and Lofa counties. Vaccinators provided mothers bringing infants for routine immunization with targeted family planning and immunization messages and same-day referrals to co-located family planning services. In February 2013, we compared service statistics for family planning and immunization during the pilot against the previous year's statistics. We also conducted in-depth interviews with service providers and other personnel and focus group discussions with clients. Results showed that referral acceptance across the facilities varied from 10% to 45% per month, on average. Over 80% of referral acceptors completed the family planning visit that day, of whom over 90% accepted a contraceptive method that day. The total number of new contraceptive users at participating facilities increased by 73% in Bong and by 90% in Lofa. Women referred from immunization who accepted family planning that day accounted for 44% and 34% of total new contraceptive users in Bong and Lofa, respectively. In Lofa, pilot sites administered 35% more Penta 1 and 21% more Penta 3 doses during the pilot period compared with the same period of the previous year, while Penta 1 and Penta 3 administration decreased in non-pilot facilities. In Bong, there was little difference in the number of Penta 1 and Penta 3 doses administered between pilot and non-pilot facilities. In both counties, Penta 1 to Penta 3 dropout rates increased at pilot sites but not in non-pilot facilities, possibly due to higher than average background dropout rates at pilot sites prior to the intervention in Lofa and the disproportionate effect of data from 1 large facility in Bong. The project provided considerable basic support to assess this proof of concept. However, results suggest that introducing a simple model that is minimally disruptive to existing immunization service delivery can facilitate integration. The model is currently being scaled-up to other counties in Liberia, which could potentially contribute to increased postpartum contraceptive uptake, leading to longer birth intervals and improved health outcomes for children and mothers

Female Health Workers at the Doorstep: A Pilot of Community-Based Maternal, Newborn, and Child Health Service Delivery in Northern Nigeria

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Deployment of resident female Community Health Extension Workers (CHEWs) to a remote rural community led to major and sustained increases in service utilization, including antenatal care and facility-based deliveries. Key components to success: (1) providing an additional rural residence allowance to help recruit and retain CHEWs; (2) posting the female CHEWs in pairs to avoid isolation and provide mutual support; (3) ensuring supplies and transportation means for home visits; and (4) allowing CHEWs to perform deliveries.

Engaging Communities With a Simple Tool to Help Increase Immunization Coverage

Use of a simple, publicly placed tool that monitors vaccination coverage in a community has potential to broaden program coverage by keeping both the community and the health system informed about every infant's vaccination status.

Manish Jain, Gunjan Taneja, Ruhul Amin, Robert Steinglass, Michael Favin
Glob Health Sci Pract 2015;3(1):117-125. http://dx.doi.org/10.9745/GHSP-D-14-00180
Abstract

Global Health Governance
[Accessed 7 March 2015]
http://blogs.shu.edu/ghg/category/complete-issues/summer-2013/
[No new relevant content]

Global Public Health
Volume 10, Issue 4, 2015
http://www.tandfonline.com/toc/rgph20/current#.VPudJy5nBhU
Endgame for polio eradication? Options for overcoming social and political factors in the progress to eradicating polio
Pavan V. Ganapathirajuab*, Christiaan B. Morssinkc & James Plumbd
pages 463-473
DOI:10.1080/17441692.2014.994655
Abstract
In 1988, the Global Polio Eradication Initiative (GPEI) was launched with the goal of eradicating polio by the year 2000. After 25 years, several dynamics still challenge this large public health campaign with new cases of polio being reported annually. We examine the roots of this initiative to eradicate polio, its scope, the successes and setbacks during the last 25 years and reflect on the current state of affairs. We examine the social and political factors that are barriers to polio eradication. Options are discussed for solving the current impasse of polio eradication: using force, respecting individual freedoms and gaining support from those vulnerable to fundamentalist 'propaganda'. The travails of the GPEI indicate the need for expanding the Convention on the Rights of the Child to address situations of war and civic strife. Such a cultural and structural reference will provide the basis for global stakeholders to engage belligerent local actors whose local political conflicts are barriers to the eradication of polio. Disregard for these actors will result in stagnation of polio eradication policy, delaying eradication beyond 2018.

Globalization and Health
[Accessed 7 March 2015]
http://www.globalizationandhealth.com/
[No new relevant content]

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March 2015; Volume 34, Issue 3
http://content.healthaffairs.org/content/current
People In Sub-Saharan Africa Rate Their Health And Health Care Among The Lowest In The World
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2Robert Tortora was principal scientist and chief methodologist at the Gallup Organization, in Washington, D.C., when this article was written. He is now a senior fellow of survey methodology at ICF International, in Rockville, Maryland.

Abstract

The health of people in sub-Saharan Africa is a major global concern. However, data are weak, and little is known about how people in the region perceive their health or their health care. We used data from the Gallup World Poll in 2012 to document sub-Saharan Africans' perceived health status, their satisfaction with health care, their contact with medical professionals, and the priority they attach to health care. In comparison to other regions of the world, sub-Saharan Africa has the lowest ratings for well-being and the lowest satisfaction with health care. It also has the second-lowest perception of personal health, after only the former Soviet Union and its Eastern European satellites. HIV prevalence is positively correlated with perceived improvements in health care in countries with high prevalence. This is consistent with an improvement in at least some health care services as a result of the largely aid-funded rollout of antiretroviral treatment. Even so, sub-Saharan Africans do not prioritize health care as a matter of policy, although donors are increasingly shifting their aid efforts in the region toward health.

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 - Issue 02 - April 2015
http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue

[New issue; No relevant content]

Health Policy and Planning

Volume 30 Issue 2 March 2015
http://heapol.oxfordjournals.org/content/current

Integrating mental health and social development in theory and practice

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Accepted December 17, 2013.

Abstract

In many low and middle income countries, attention to mental illness remains compartmentalized and consigned as a matter for specialist policy. Despite great advances in global mental health, mental health policy and practice dovetail only to a limited degree with social development efforts. They often lag behind broader approaches to health and development. This gap ignores the small but growing evidence that social development unavoidably impacts the mental health of those affected, and that this influence can be both positive and negative. This article examines the theoretical and practical challenges that need to

be overcome for a more effective integration of social development and mental health policy. From a theoretical perspective, this article demonstrates compatibility between social development and mental health paradigms. In particular, the capability approach is shown to provide a strong framework for integrating mental health and development. Yet, capability-oriented critiques on 'happiness' have recently been applied to mental health with potentially detrimental outcomes. With regard to policy and practice, horizontal and vertical integration strategies are suggested. Horizontal strategies require stronger devolution of mental health care to the primary care level, more unified messages regarding mental health care provision and the gradual expansion of mental health packages of care. Vertical integration refers to the alignment of mental health with related policy domains (particularly the social, economic and political domains). Evidence from mental health research reinforces aspects of social development theory in a way that can have tangible implications on practice. First, it encourages a focus on avoiding exclusion of those affected by or at risk of mental illness. Secondly, it underscores the importance of the process of implementation as an integral component of successful policies. Finally, by retaining a focus on the individual, it seeks to avoid uneven approaches to development.

Overcoming challenges to sustainable immunization financing: early experiences from GAVI graduating countries

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Abstract

Over the 5-year period ending in 2018, 16 countries with a combined birth cohort of over 6 million infants requiring life-saving immunizations are scheduled to transition (graduate) from outside financial and technical support for a number of their essential vaccines. This support has been provided over the past decade by the GAVI Alliance. Will these 16 countries be able to continue to sustain these vaccination efforts? To address this issue, GAVI and its partners are supporting transition planning, entailing country assessments of readiness to graduate and intensive dialogue with national officials to ensure a smooth transition process. This approach was piloted in Bhutan, Republic of Congo, Georgia, Moldova and Mongolia in 2012. The pilot showed that graduating countries are highly heterogeneous in their capacity to assume responsibility for their immunization programmes. Although all possess certain strengths, each country displayed weaknesses in some of the following areas: budgeting for vaccine purchase, national procurement practices, performance of national regulatory agencies, and technical capacity for vaccine planning and advocacy. The 2012 pilot experience further demonstrated the value of transition planning processes and tools. As a result, GAVI has decided to continue with transition planning in 2013 and beyond. As the graduation process advances, GAVI and graduating countries should continue to contribute to global collective thinking about how developing countries can successfully end their dependence on donor aid and achieve self-sufficiency.

Health seeking behaviour and the related household out-of-pocket expenditure for chronic non-communicable diseases in rural Malawi

Qun Wang, Stephan Brenner, Gerald Leppert, Thomas Hastings Banda, Olivier Kalmus, and Manuela De Allegri
Health Policy Plan. (2015) 30 (2): 242-252 doi:10.1093/heapol/czu004
Abstract

Policy options for pharmaceutical pricing and purchasing: issues for low- and middle-income countries

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Author Affiliations
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Abstract
Pharmaceutical expenditure is rising globally. Most high-income countries have exercised pricing or purchasing strategies to address this pressure. Low- and middle-income countries (LMICs), however, usually have less regulated pharmaceutical markets and often lack feasible pricing or purchasing strategies, notwithstanding their wish to effectively manage medicine budgets. In high-income countries, most medicines payments are made by the state or health insurance institutions. In LMICs, most pharmaceutical expenditure is out-of-pocket which creates a different dynamic for policy enforcement. The paucity of rigorous studies on the effectiveness of pharmaceutical pricing and purchasing strategies makes it especially difficult for policy makers in LMICs to decide on a course of action. This article reviews published articles on pharmaceutical pricing and purchasing policies. Many policy options for medicine pricing and purchasing have been found to work but they also have attendant risks. No one option is decisively preferred; rather a mix of options may be required based on country-specific context. Empirical studies in LMICs are lacking. However, risks from any one policy option can reasonably be argued to be greater in LMICs which often lack strong legal systems, purchasing and state institutions to underpin the healthcare system. Key factors are identified to assist LMICs improve their medicine pricing and purchasing systems.

Health Research Policy and Systems
http://www.health-policy-systems.com/content
[Accessed 7 March 2015]
Research

How does context influence performance of community health workers in low- and middle-income countries? Evidence from the literature

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Author Affiliations
Health Research Policy and Systems 2015, 13:13 doi:10.1186/s12961-015-0001-3
Published: 7 March 2015
Abstract (provisional)
Background

Community health workers (CHWs) are increasingly recognized as an integral component of the health workforce needed to achieve public health goals in low- and middle-income countries (LMICs). Many factors intersect to influence CHW performance. A systematic review with a narrative analysis was conducted to identify contextual factors influencing performance of CHWs.
Methods
We searched six databases for quantitative, qualitative, and mixed-methods studies that included CHWs working in promotional, preventive or curative primary health care services in LMICs. We differentiated CHW performance outcome measures at two levels: CHW level and end-user level. Ninety-four studies met the inclusion criteria and were double read to extract data relevant to the context of CHW programmes. Thematic coding was conducted and evidence on five main categories of contextual factors influencing CHW performance was synthesized.
Results
Few studies had the influence of contextual factors on CHW performance as their primary research focus. Contextual factors related to community (most prominently), economy, environment, and health system policy and practice were found to influence CHW performance. Socio-cultural factors (including gender norms and values and disease related stigma), safety and security and education and knowledge level of the target group were community factors that influenced CHW performance. Existence of a CHW policy, human resource policy legislation related to CHWs and political commitment were found to be influencing factors within the health system policy context. Health system practice factors included health service functionality, human resources provisions, level of decision-making, costs of health services, and the governance and coordination structure. All contextual factors can interact to shape CHW performance and affect the performance of CHW interventions or programmes.
Conclusions
Research on CHW programmes often does not capture or explicitly discuss the context in which CHW interventions take place. This synthesis situates and discusses the influence of context on CHW and programme performance. Future health policy and systems research should better address the complexity of contextual influences on programmes. This insight can help policy makers and programme managers to develop CHW interventions that adequately address and respond to context to optimise performance

Editorial

Health research improves healthcare: now we have the evidence and the chance to help the WHO spread such benefits globally

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Published: 3 March 2015

Abstract

There has been a dramatic increase in the body of evidence demonstrating the benefits that come from health research. In 2014, the funding bodies for higher education in the UK conducted an assessment of research using an approach termed the Research Excellence Framework (REF). As one element of the REF, universities and medical schools in the UK submitted 1,621 case studies claiming to show the impact of their health and other life sciences research conducted over the last 20 years. The recently published results show many case studies were judged positively as providing examples of the wide range and extensive nature of

the benefits from such research, including the development of new treatments and screening programmes that resulted in considerable reductions in mortality and morbidity.
Analysis of specific case studies yet again illustrates the international dimension of progress in health research; however, as has also long been argued, not all populations fully share the benefits. In recognition of this, in May 2013 the World Health Assembly requested the World Health Organization (WHO) to establish a Global Observatory on Health Research and Development (R&D) as part of a strategic work-plan to promote innovation, build capacity, improve access, and mobilise resources to address diseases that disproportionately affect the world's poorest countries.
As editors of Health Research Policy and Systems (HARPS), we are delighted that our journal has been invited to help inform the establishment of the WHO Global Observatory through a Call for Papers covering a range of topics relevant to the Observatory, including topics on which HARPS has published articles over the last few months, such as approaches to assessing research results, measuring expenditure data with a focus on R&D, and landscape analyses of platforms for implementing R&D. Topics related to research capacity building may also be considered. The task of establishing a Global Observatory on Health R&D to achieve the specified objectives will not be easy; nevertheless, this Call for Papers is well timed – it comes just at the point where the evidence of the benefits from health research has been considerably strengthened.

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)
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http://www.tandfonline.com/toc/khvi20/11/1#.VPJsQS5nBhU
[Reviewed earlier]

Infectious Agents and Cancer
[Accessed 7 March 2015]
http://www.infectagentscancer.com/content
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Infectious Diseases of Poverty
[Accessed 7 March 2015]
http://www.idpjournal.com/content
[No new relevant content]

International Health
Volume 7 Issue 2 March 2015
http://inthealth.oxfordjournals.org/content/current
Special issue: Digital methods in epidemiology
Digital methods in epidemiology can transform disease control
Extract
Modern society has been transformed by the digital revolution through cellular phones for communication, remote sensing of weather and other terrestrial data, cheap and plentiful digital computation and data storage, genomic sequencing and analysis, GPS for geolocation and

navigation, and many other marvels. These advances have been concurrent with major changes in the burden, dynamics and distributions of diseases. The burden of disease remains intolerably high in much of the world,1 and current challenges facing epidemiology include reducing the prevalence of both communicable and non-communicable diseases,1 completing the Global Polio Eradication Initiative,2 developing strategies to control and eliminate malaria,2,3 and responding to outbreaks of emerging infectious diseases such as the recent Ebola epidemic.4 In this special issue of International Health, the authors illustrate both the ways in which modern digital methods are already being applied to these current challenges in epidemiology and also the opportunities for even greater impact.

Advancing digital methods in the fight against communicable diseases

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Abstract

Important advances are being made in the fight against communicable diseases by using new digital tools. While they can be a challenge to deploy at-scale, GPS-enabled smartphones, electronic dashboards and computer models have multiple benefits. They can facilitate program operations, lead to new insights about the disease transmission and support strategic planning. Today, tools such as these are used to vaccinate more children against polio in Nigeria, reduce the malaria burden in Zambia and help predict the spread of the Ebola epidemic in West Africa.

The promise of reverse vaccinology

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Abstract

Reverse vaccinology (RV) is a computational approach that aims to identify putative vaccine candidates in the protein coding genome (proteome) of pathogens. RV has primarily been applied to bacterial pathogens to identify proteins that can be formulated into subunit vaccines, which consist of one or more protein antigens. An RV approach based on a filtering method has already been used to construct a subunit vaccine against Neisseria meningitidis serogroup B that is now registered in several countries (Bexsero). Recently, machine learning methods have been used to improve the ability of RV approaches to identify vaccine candidates. Further improvements related to the incorporation of epitope-binding annotation and gene expression data are discussed. In the future, it is envisaged that RV approaches will facilitate rapid vaccine design with less reliance on conventional animal testing and clinical trials in order to curb the threat of antibiotic resistance or newly emerged outbreaks of bacterial origin.

Poverty, health and satellite-derived vegetation indices: their inter-spatial relationship in West Africa

Luigi Sedda, Andrew J. Tatem, David W. Morley, Peter M. Atkinson, Nicola A. Wardrop, Carla Pezzulo, Alessandro Sorichetta, Joanna Kuleszo, and David J. Rogers

Int. Health (2015) 7 (2): 99-106 doi:10.1093/inthealth/ihv005
Abstract
Background
Previous analyses have shown the individual correlations between poverty, health and satellite-derived vegetation indices such as the normalized difference vegetation index (NDVI). However, generally these analyses did not explore the statistical interconnections between poverty, health outcomes and NDVI.
Methods
In this research aspatial methods (principal component analysis) and spatial models (variography, factorial kriging and cokriging) were applied to investigate the correlations and spatial relationships between intensity of poverty, health (expressed as child mortality and undernutrition), and NDVI for a large area of West Africa.
Results
This research showed that the intensity of poverty (and hence child mortality and nutrition) varies inversely with NDVI. From the spatial point-of-view, similarities in the spatial variation of intensity of poverty and NDVI were found.
Conclusions
These results highlight the utility of satellite-based metrics for poverty models including health and ecological components and, in general for large scale analysis, estimation and optimisation of multidimensional poverty metrics. However, it also stresses the need for further studies on the causes of the association between NDVI, health and poverty. Once these relationships are confirmed and better understood, the presence of this ecological component in poverty metrics has the potential to facilitate the analysis of the impacts of climate change on the rural populations afflicted by poverty and child mortality.

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http://ije.oxfordjournals.org/content/current
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International Journal of Infectious Diseases
April 2015 Volume 33, p1
http://www.ijidonline.com/current
[Reviewed earlier]

JAMA
http://jama.jamanetwork.com/issue.aspx
Online First
March 05, 2015
Editorial
Emergency Treatment for Exposure to Ebola Virus: The Need to Fast-Track Promising Vaccines
Thomas W. Geisbert, PhD.
JAMA. Published online March 05, 2015. doi:10.1001/jama.2015.2057

Ebola virus is among the most deadly pathogens, with case fatality rates of up to 90%.[1] Ebola virus is categorized as a tier 1 pathogen by the US government because of its potential for deliberate misuse with significant potential for mass casualties. The current outbreak of Ebola virus in West Africa with more than 23 000 cases and 9000 deaths[2] also demonstrates the long-underestimated public health threat that Ebola virus poses as a natural human pathogen. There are no licensed vaccines or postexposure treatments for combating Ebola virus. However, substantial progress has been made in developing vaccines and antivirals that can protect laboratory animals against lethal disease.[1,3] Advancing these interventions for human use is a matter of utmost urgency.

In this issue of JAMA, Lai et al[4] report the use of a first-generation recombinant vesicular stomatitis virus–based Ebola vaccine (VSVΔG-ZEBOV)[5] to treat a physician who experienced a needlestick in an Ebola treatment unit in Sierra Leone during the current Ebola virus outbreak. A single dose of the VSVΔG-ZEBOV vaccine was administered approximately 43 hours after the potential exposure. The patient experienced a transient febrile syndrome after vaccination. Importantly, no evidence of Ebola virus infection was detected, and the vaccine elicited strong innate and Ebola virus–specific adaptive immune responses. Most significantly, the vaccine, which expresses the surface glycoprotein of Ebola virus, was able to induce an IgG antibody response against the Ebola virus glycoprotein at a level that has been associated with protection of nonhuman primates.[5]

It is difficult to draw any definitive conclusions from a single case report. The inability to detect evidence of Ebola virus infection most likely is because there was not an actual exposure; however, it cannot be completely ruled out that the intervention was effective in controlling Ebola virus replication. Even though this patient experienced some adverse events after vaccination, the patient reported having traveler's diarrhea prior to receiving the VSVΔG-ZEBOV vaccine; therefore, it is also not possible to draw any strong conclusions regarding any adverse events from this case in regard to the safety of the vaccine. This is the second time that the VSVΔG-ZEBOV vaccine has been used to treat a potential exposure to Ebola virus. The initial use occurred in 2009 for a laboratory worker in Germany[6] and also involved a needlestick injury. The results of that incident were nearly identical; however, the severity of adverse events following vaccination was less notable in the German case compared with the patient in the case report by Lai et al...[4]

Preliminary Communication

Emergency Postexposure Vaccination With Vesicular Stomatitis Virus–Vectored Ebola Vaccine After Needlestick

Lilin Lai, MD, Richard Davey, MD, Allison Beck, MPAS, et al.

JAMA. Published online March 05, 2015. doi:10.1001/jama.2015.1995

Abstract

Importance

Safe and effective vaccines and drugs are needed for the prevention and treatment of Ebola virus disease, including following a potentially high-risk exposure such as a needlestick.

Objective

To assess response to postexposure vaccination in a health care worker who was exposed to the Ebola virus.

Design and Setting

Case report of a physician who experienced a needlestick while working in an Ebola treatment unit in Sierra Leone on September 26, 2014. Medical evacuation to the United States was rapidly initiated. Given the concern about potentially lethal Ebola virus disease, the patient was offered, and provided his consent for, postexposure vaccination with an experimental vaccine

available through an emergency Investigational New Drug application. He was vaccinated on September 28, 2014.
Interventions
The vaccine used was VSVΔG-ZEBOV, a replicating, attenuated, recombinant vesicular stomatitis virus (serotype Indiana) whose surface glycoprotein gene was replaced by the Zaire Ebola virus glycoprotein gene. This vaccine has entered a clinical trial for the prevention of Ebola in West Africa.
Results
The vaccine was administered 43 hours after the needlestick occurred. Fever and moderate to severe symptoms developed 12 hours after vaccination and diminished over 3 to 4 days. The real-time reverse transcription polymerase chain reaction results were transiently positive for vesicular stomatitis virus nucleoprotein gene and Ebola virus glycoprotein gene (both included in the vaccine) but consistently negative for Ebola virus nucleoprotein gene (not in the vaccine). Early postvaccination cytokine secretion and T lymphocyte and plasmablast activation were detected. Subsequently, Ebola virus glycoprotein-specific antibodies and T cells became detectable, but antibodies against Ebola viral matrix protein 40 (not in the vaccine) were not detected.
Conclusions and Relevance
It is unknown if VSVΔG-ZEBOV is safe or effective for postexposure vaccination in humans who have experienced a high-risk occupational exposure to the Ebola virus, such as a needlestick. In this patient, postexposure vaccination with VSVΔG-ZEBOV induced a self-limited febrile syndrome that was associated with transient detection of the recombinant vesicular stomatitis vaccine virus in blood. Strong innate and Ebola-specific adaptive immune responses were detected after vaccination. The clinical syndrome and laboratory evidence were consistent with vaccination response, and no evidence of Ebola virus infection was detected.

JAMA - March 3, 2015, Vol 313, No. 9
[No new relevant content]

JAMA Pediatrics
March 2015, Vol 169, No. 3
http://archpedi.jamanetwork.com/issue.aspx
Viewpoint / March 2015
A Landmark Report on Improving Medicines for Children
Geert W. 't Jong, MD, PhD1,2; Terry P. Klassen, MD, MSc, FRCPC1,2; Stuart M. MacLeod, BSc(Med), MD, PhD, FRCPC3
[+] Author Affiliations
Extract
This Viewpoint discusses the publication of the Council of Canadian Academies report "Improving Medicines for Children in Canada."
Children have been classified as "therapeutic orphans" for more than 50 years, but the pediatric community has made important strides toward evidence-based safe and effective drug therapy for children through improved legislation, increased quantity and quality of research, and better stakeholder community involvement. In September 2014, another major step forward was taken with publication of the Council of Canadian Academies report "Improving Medicines for Children in Canada."1 An international Expert Panel drafted the report, and many North American and European authorities participated in the final review. The Council of

Canadian Academies was asked by Canada's federal government to review the status of pediatric therapeutics in Canada, based on the following question: "What is the state of clinical pharmacology, in Canada and abroad, that can be applied to the ethical development of safe and effective pharmaceuticals and biologics labeled as therapies for infants, children and youth?"1

Journal of Community Health
Volume 40, Issue 2, April 2015
http://link.springer.com/journal/10900/40/2/page/1
Commentary
Ebola Therapy and Health Equity
Neil J. Nusbaum
Abstract
Current care for Ebola patients in resource poor countries is hampered by a lack of resources to isolate patients and their close contacts. The current Ebola epidemic offers the opportunity to harvest convalescent serum to help contain this and future outbreaks. A systemic and just process to accomplish this goal can incorporate procedures to improve care for current Ebola patients and their close contacts.
Factors Impacting Influenza Vaccination of Urban Low-Income Latino Children Under Nine Years Requiring Two Doses in the 2010–2011 Season
Annika M. Hofstetter, Angela Barrett, Melissa S. Stockwell
Abstract
The Advisory Committee on Immunization Practices (ACIP) recommends that certain children under 9 years of age receive two influenza vaccine doses in a season for optimal protection. Recent data indicate that many of these children fail to receive one or both of these needed doses. Contributing factors to under-vaccination of this population remain unclear. Caregivers of children aged 6 months–8 years requiring two influenza vaccine doses in the 2010–2011 season were identified from households enrolled in four urban Head Start programs. Recruitment and survey administration were conducted between March and June 2011. The impact of caregiver, provider, and practice-based factors on influenza vaccine receipt was assessed using bivariate and multivariable logistic regression analyses. Caregivers ($n = 128$) were predominantly mothers, Latina, Spanish-speaking, and non-U.S. born. Few children received one (31 %) or both (7 %) influenza vaccine doses. Caregivers who discussed influenza vaccination with providers were more likely to know their child needed two doses (55 vs. 35 %, $p < 0.05$) and have a fully vaccinated child (11 vs. 0 %, $p < 0.05$). Among caregivers whose child received the first dose, those who reported being told when to return for the second dose were also more likely to have a fully vaccinated child (35 vs. 0 %, $p = 0.05$). Belief in influenza vaccine effectiveness was positively associated with vaccination ($p < 0.001$), while safety concerns were negatively associated ($p < 0.05$). This study highlights the importance of provider-family communication about the two-dose regimen as well as influenza vaccine effectiveness and safety.

Journal of Epidemiology & Community Health
March 2015, Volume 69, Issue 3
http://jech.bmj.com/content/current
Child health

The impact of the Iraq War on neonatal polio immunisation coverage: a quasi-experimental study

Valeria Cetorelli
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Abstract
Background The public health consequences of the Iraq War (2003–2011) have remained difficult to quantify, mainly due to a scarcity of adequate data. This paper is the first to assess whether and to what extent the war affected neonatal polio immunisation coverage.
Method The study relies on retrospective neonatal polio vaccination histories from the 2000, 2006 and 2011 Iraq Multiple Indicator Cluster Surveys (N=64 141). Pooling these surveys makes it possible to reconstruct yearly trends in immunisation coverage from 1996 to 2010. The impact of the war is identified with a difference-in-difference approach contrasting immunisation trends in the autonomous Kurdish provinces, which remained relatively safe during the war, with trends in the central and southern provinces, where violence and disruption were pervasive.
Results After controlling for individual and household characteristics, year of birth and province of residence, children exposed to the war were found to be 21.5 percentage points (95% CI −0.341 to −0.089) less likely to have received neonatal polio immunisation compared with non-exposed children.
Conclusions The decline in neonatal polio immunisation coverage is part of a broader war-induced deterioration of routine maternal and newborn health services. Postwar strategies to promote institutional deliveries and ensure adequate vaccine availability in primary health facilities could increase dramatically the percentage of newborns immunised.

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

Journal of Global Infectious Diseases (JGID)
January-March 2015 Volume 7 | Issue 1 Page Nos. 1-50
http://www.jgid.org/currentissue.asp?sabs=n
[Reviewed earlier]

Journal of Health Care for the Poor and Underserved (JHCPU)
Volume 26, Number 1, February 2015
http://muse.jhu.edu/journals/journal_of_health_care_for_the_poor_and_underserved/toc/hpu.26.1.html
[Reviewed earlier]

Journal of Health Organization and Management
Volume 17, Issue 1, February 2015
http://link.springer.com/journal/10903/17/1/page/1

[Reviewed earlier]

Journal of Immigrant and Minority Health
Volume 17, Issue 1, February 2015
http://link.springer.com/journal/10903/17/1/page/1
[Reviewed earlier]

Journal of Immigrant & Refugee Studies
Volume 12, Issue 4, 2014
http://www.tandfonline.com/toc/wimm20/current#.VFWeF8l4WF9
Special Issue: New Forms of Intolerance in European Political Life
[Reviewed earlier]

Journal of Infectious Diseases
Volume 211 Issue 5 March 1, 2015
http://jid.oxfordjournals.org/content/current
[Reviewed earlier]

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
[Reviewed earlier]

Journal of Medical Ethics
March 2015, Volume 41, Issue 3
http://jme.bmj.com/content/current
[Reviewed earlier]

Journal of Medical Internet Research
Vol 17, No 2 (2015): February
http://www.jmir.org/2015/2
[Reviewed earlier]

Journal of Medical Microbiology
February 2015; 64 (Pt 2)
http://jmm.sgmjournals.org/content/current
[Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)

Volume 4 Issue 1 March 2015
http://jpids.oxfordjournals.org/content/current
[Reviewed earlier]

Journal of Pediatrics
March 2015 Volume 166, Issue 3, p507-782
http://www.jpeds.com/current

Explaining alleged pertussis vaccine associated neurologic disorders
Sarah S. Long, MD
DOI: http://dx.doi.org/10.1016/j.jpeds.2015.01.010
Extract
In 1986, the National Childhood Vaccine Injury Act established the Vaccine Injury Compensation Program to compensate children and adults or to adjudicate claims of injury related to vaccines. Along with such benefits, healthcare providers who administer vaccines are mandated to maintain vaccination records and to report certain adverse events associated with covered immunizations. In this issue of The Journal, investigators from Children's National Medical Center, the Division of Vaccine Injury Compensation of the Department of Health and Human Services, and the National Institute of Neurologic Disorders of the National Institutes of Health report the findings of 165 claims of children younger than 2 years of age with seizures or encephalopathy as an alleged vaccine-related injury from 1995 through 2005.

Post-Licensure Monitoring to Evaluate Vaccine Safety
Annabelle de St Maurice, MD
Division of Infectious Diseases, Department of Pediatrics, Vanderbilt Vaccine Research Program, Vanderbilt University School of Medicine, Nashville, Tennessee
Kathryn M. Edwards, MD
Division of Infectious Diseases, Department of Pediatrics, Vanderbilt Vaccine Research Program, Vanderbilt University School of Medicine, Nashville, Tennessee
DOI: http://dx.doi.org/10.1016/j.jpeds.2014.12.031
Extract
Pertussis, or whooping cough, is caused by a gram-negative rod, Bordetella pertussis. Typically, pertussis causes a respiratory illness characterized by prolonged cough in adults and children. In infants, it can be complicated by apnea, pneumonia, pulmonary hypertension, and neurologic symptoms, including encephalopathy and seizures. Prior to the introduction of pertussis vaccine in the US, there were about 157 cases of pertussis per 100 000 people each year, with 1.5 deaths per 1000 infants less than 1 year of age.

Seizures, Encephalopathy, and Vaccines: Experience in the National Vaccine Injury Compensation Program
Tarannum M. Lateef, MD, MPH, Rosemary Johann-Liang, MD, Himanshu Kaulas, MD, Rakibul Hasan, MD, Karen Williams, MS, Vito Caserta, MD, Karin B. Nelson, MD
Received: May 20, 2014; Received in revised form: September 12, 2014; Accepted: October 22, 2014; Published Online: December 02, 2014
DOI: http://dx.doi.org/10.1016/j.jpeds.2014.10.054
Abstract
Objectives
To describe the demographic and clinical characteristics of children for whom claims were filed with the National Vaccine Injury Compensation Program (VICP) alleging seizure disorder and/or encephalopathy as a vaccine injury.

Study design
The National VICP within the Department of Health and Human Services compensates individuals who develop medical problems associated with a covered immunization. We retrospectively reviewed medical records of children younger than 2 years of age with seizures and/or encephalopathy allegedly caused by an immunization, where a claim was filed in the VICP between 1995 through 2005.
Results
The VICP retrieved 165 claims that had sufficient clinical information for review. Approximately 80% of these alleged an injury associated with whole-cell diphtheria, pertussis (whooping cough), and tetanus or tetanus, diphtheria toxoids, and acellular pertussis vaccine. Pre-existing seizures were found in 13% and abnormal findings on a neurologic examination before the alleged vaccine injury in 10%. A final diagnostic impression of seizure disorder was established in 69%, of whom 17% (28 patients) had myoclonic epilepsy, including possible severe myoclonic epilepsy of infancy. Specific conditions not caused by immunization, such as tuberous sclerosis and cerebral dysgenesis, were identified in 16% of subjects.
Conclusion
A significant number of children with alleged vaccine injury had pre-existing neurologic or neurodevelopmental abnormalities. Among those developing chronic epilepsy, many had clinical features suggesting genetically determined epilepsy. Future studies that include genotyping may allow more specific therapy and prognostication, and enhance public confidence in vaccination.

Journal of Public Health Policy
Volume 36, Issue 1 (February 2015)
http://www.palgrave-journals.com/jphp/journal/v36/n1/index.html
[Reviewed earlier]

Journal of the Royal Society – Interface
06 February 2015; volume 12, issue 103
http://rsif.royalsocietypublishing.org/content/current
[Reviewed earlier]

Journal of Virology
February 2015, volume 89, issue 3
http://jvi.asm.org/content/current
[Reviewed earlier]

The Lancet
Mar 07, 2015 Volume 385 Number 9971 p829-914 e16-e20
http://www.thelancet.com/journals/lancet/issue/current
Comment
Morality in a time of Ebola
Arthur L Caplan
Published Online: 19 February 2015

Summary
The first true epidemic of Ebola led to widespread panic. The virus appeared in so many countries in 2014—including Guinea, Liberia, Mali, Nigeria, Senegal, Sierra Leone, Spain, and the USA—that WHO, officials at the US National Institutes of Health and Centers for Disease Control and Prevention, and many other government officials around the world declared the epidemic to be out of control.1,2 Talk of desperation and apocalypse with reference to Ebola is not uncommon.3 Previous Ebola outbreaks were rapidly contained through a combination of local attentiveness, the availability of resources, focused public education, and a bit of luck.

The Lancet Global Health
Volume 3, No. 3, e162–e168, March 2015
http://www.thelancet.com/journals/langlo/issue/current
[Reviewed earlier]

The Lancet Infectious Diseases
Mar 2015 Volume 15 Number 3 p249-360
http://www.thelancet.com/journals/laninf/issue/current
Editorial
Global harmonisation in vaccine price
The Lancet Infectious Diseases
Summary
On Jan 20, 2015, Médecins Sans Frontières published the second edition of the report The right shot: bringing down barriers to affordable and adapted vaccines. The report highlighted the lack of a rational pricing system for vaccines that serves all countries and populations, and, as a consequence, private and public health providers struggle to sustain the costs of immunisation campaigns in many settings. Several factors, such as limited information on vaccine prices, introduction of costly new vaccines, absence of competition in vaccine production, and a paucity of vaccine products suited for low-resource settings, have created a market in which children in many countries are unprotected against life-threatening—but preventable—diseases.
Comment
Novel observational study designs with new influenza vaccines
Eelko Hak
Published Online: 08 February 2015
Summary
In The Lancet Infectious Diseases, Hector Izurieta and colleagues1 presented results of a cohort study in 929 730 older people (65 years and older) who received a high-dose influenza vaccine (high-dose Fluzone, Sanofi Pasteur, PA, USA, 60 µg per strain) and compared rates of influenza-related visits and hospital admissions with 1 615 545 older people who received a standard dose of the same vaccine (15 µg per strain). The high-dose vaccine seemed to be 22% more effective than the standard-dose vaccine.
Comparative effectiveness of high-dose versus standard-dose influenza vaccines in US residents aged 65 years and older from 2012 to 2013 using Medicare data: a retrospective cohort analysis

Hector S Izurieta, Nicole Thadani, David K Shay, Yun Lu, Aaron Maurer, Ivo M Foppa, Riley Franks, Douglas Pratt, Richard A Forshee, Thomas MaCurdy, Chris Worrall, Andrew E Howery, Jeffrey Kelman
Summary Full-Text HTML PDF

Effect of use of 13-valent pneumococcal conjugate vaccine in children on invasive pneumococcal disease in children and adults in the USA: analysis of multisite, population-based surveillance

Matthew R Moore, Ruth Link-Gelles, William Schaffner, Ruth Lynfield, Catherine Lexau, Nancy M Bennett, Susan Petit, Shelley M Zansky, Lee H Harrison, Arthur Reingold, Lisa Miller, Karen Scherzinger, Ann Thomas, Monica M Farley, Elizabeth R Zell, Thomas H Taylor, Tracy Pondo, Loren Rodgers, Lesley McGee, Bernard Beall, James H Jorgensen, Cynthia G Whitney
Summary Full-Text HTML PDF

Chains of transmission and control of Ebola virus disease in Conakry, Guinea, in 2014: an observational study

Ousmane Faye, Pierre-Yves Boëlle, Emmanuel Heleze, Oumar Faye, Cheikh Loucoubar, N'Faly Magassouba, Barré Soropogui, Sakoba Keita, Tata Gakou, El Hadji Ibrahima Bah, Lamine Koivogui, Amadou Alpha Sall, Simon Cauchemez
Summary Full-Text HTML PDF

Review

The development of global vaccine stockpiles

Dr Catherine Yen, MD, Terri B Hyde, MD, Alejandro J Costa, MSc, Katya Fernandez, MSc, John S Tam, PhD, Stéphane Hugonnet, MD, Anne M Huvos, JD, Philippe Duclos, PhD, Vance J Dietz, MD, Brenton T Burkholder, MD
Published Online: 05 February 2015

Summary

Global vaccine stockpiles, in which vaccines are reserved for use when needed for emergencies or supply shortages, have effectively provided countries with the capacity for rapid response to emergency situations, such as outbreaks of yellow fever and meningococcal meningitis. The high cost and insufficient supply of many vaccines, including oral cholera vaccine and pandemic influenza vaccine, have prompted discussion on expansion of the use of vaccine stockpiles to address a wider range of emerging and re-emerging diseases. However, the decision to establish and maintain a vaccine stockpile is complex and must take account of disease and vaccine characteristics, stockpile management, funding, and ethical concerns, such as equity. Past experience with global vaccine stockpiles provide valuable information about the processes for their establishment and maintenance. In this Review we explored existing literature and stockpile data to discuss the lessons learned and to inform the development of future vaccine stockpiles.

Personal View

Emergency Ebola response: a new approach to the rapid design and development of vaccines against emerging diseases

Claire M Tully, BA[Mod], Teresa Lambe, PhD, Prof Sarah C Gilbert, PhD, Prof Adrian V S Hill, DM
Published Online: 13 January 2015

1. *Summary*

The epidemic of Ebola virus disease has spread at an alarming rate despite containment efforts. As a result, unprecedented large-scale international response efforts have been made in an attempt to gain control of the outbreak and reduce transmission. Several international consortia have been formed in a remarkable worldwide collaborative effort to expedite trials of two candidate Ebola virus vaccines: cAd3-EBOZ and rVSV-EBOV. In parallel, both vaccines are being

manufactured in large amounts to enable future rapid deployment for management of the crisis.

Maternal and Child Health Journal
Volume 19, Issue 3, March 2015
http://link.springer.com/journal/10995/19/3/page/1
[New issue; No relevant content]

Medical Decision Making (MDM)
February 2015; 35 (2)
http://mdm.sagepub.com/content/current
[Reviewed earlier]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
March 2015 Volume 93, Issue 1 Pages 1–222
http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1468-0009/currentissue
Op-Ed
Good Science + Good Ethics = Good Law: Five Rules for Epidemic Preparedness
LAWRENCE O. GOSTIN*
Article first published online: 5 MAR 2015
DOI: 10.1111/1468-0009.12100
[No abstract]

Nature
Volume 519 Number 7541 pp5-124 5 March 2015
http://www.nature.com/nature/current_issue.html
Editorial
Fatal fallout
The Ebola epidemic has had a dire effect on the health prospects of pregnant women.
04 March 2015
Features
Maternal health: Ebola's lasting legacy
One of the most devastating consequences of the Ebola outbreak will be its impact on maternal health.
Erika Check Hayden
04 March 2015

Nature Medicine
March 2015, Volume 21 No 3 pp199-294
http://www.nature.com/nm/journal/v21/n3/index.html
[New issue; No relevant content]

Nature Reviews Immunology
February 2015 Vol 15 No 2
http://www.nature.com/nri/journal/v15/n2/index.html
[Reviewed earlier]

New England Journal of Medicine
March 5, 2015 Vol. 372 No. 10
http://www.nejm.org/toc/nejm/medical-journal
Perspective
Making Hepatitis E a Vaccine-Preventable Disease
Eyasu Teshale, M.D., and John W. Ward, M.D.
N Engl J Med 2015; 372:899-901 March 5, 2015 DOI: 10.1056/NEJMp1415240
A hepatitis E vaccine could become a powerful new tool in the prevention and control of hepatitis E virus transmission and disease. Most immediately, it can have a role in curbing outbreaks of hepatitis E in humanitarian crises.
Original Article
Long-Term Efficacy of a Hepatitis E Vaccine
Jun Zhang, M.Sc., Xue-Feng Zhang, M.Sc., Shou-Jie Huang, M.Sc., Ting Wu, Ph.D., Yue-Mei Hu, M.Sc., Zhong-Ze Wang, B.Sc., Hua Wang, M.D., Han-Min Jiang, B.Sc., Yi-Jun Wang, M.Sc., Qiang Yan, M.Sc., Meng Guo, B.Sc., Xiao-Hui Liu, B.Sc., Jing-Xin Li, M.Sc., Chang-Lin Yang, B.Sc., Quan Tang, B.Sc., Ren-Jie Jiang, M.Sc., Hui-Rong Pan, Ph.D., Yi-Min Li, M.D., J. Wai-Kuo Shih, Ph.D., Mun-Hon Ng, Ph.D., Feng-Cai Zhu, M.Sc., and Ning-Shao Xia
N Engl J Med 2015; 372:914-922 March 5, 2015 DOI: 10.1056/NEJMoa1406011
Abstract
Background
Hepatitis E virus (HEV) is a leading cause of acute hepatitis. The long-term efficacy of a hepatitis E vaccine needs to be determined.
Methods
In an initial efficacy study, we randomly assigned healthy adults 16 to 65 years of age to receive three doses of either a hepatitis E vaccine (vaccine group; 56,302 participants) or a hepatitis B vaccine (control group; 56,302 participants). The vaccines were administered at 0, 1, and 6 months, and the participants were followed for 19 months. In this extended follow-up study, the treatment assignments of all participants remained double-blinded, and follow-up assessments of efficacy, immunogenicity, and safety were continued for up to 4.5 years.
Results
During the 4.5-year study period, 60 cases of hepatitis E were identified; 7 cases were confirmed in the vaccine group (0.3 cases per 10,000 person-years), and 53 cases in the control group (2.1 cases per 10,000 person-years), representing a vaccine efficacy of 86.8% (95% confidence interval, 71 to 94) in the modified intention-to-treat analysis. Of the participants who were assessed for immunogenicity and were seronegative at baseline, 87% of those who received three doses of the hepatitis E vaccine maintained antibodies against HEV for at least 4.5 years; HEV antibody titers developed in 9% in the control group. The rate of adverse events was similar in the two groups.
Conclusions

Immunization with this hepatitis E vaccine induced antibodies against HEV and provided protection against hepatitis E for up to 4.5 years. (Funded by the Chinese Ministry of Science and Technology and others; ClinicalTrials.gov number, NCT01014845.)

Pediatrics
March 2015, VOLUME 135 / ISSUE 3
http://pediatrics.aappublications.org/current.shtml

Advancing Informed Consent for Vulnerable Populations

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Author Affiliations
aDepartment of Pediatrics, Vanderbilt University Medical Center, Nashville, Tennessee; and
bDivision of Community Internal Medicine, Mayo Clinic, Jacksonville, Florida

Extract

Informed consent is essential for the conduct of ethical biomedical research.1 Despite its importance, obtaining informed consent is often a complex process, which raises concerns about the extent to which participants are truly informed. Effective implementation is especially difficult among research participants who have limited health literacy. Often, these potential participants are from traditionally high-risk groups, including underrepresented minorities and children. With this in mind, we suggest an innovative approach that uses low health-literacy communication strategies and visual aids to augment and potentially replace the traditional approach to informed consent.

The tension is clear. To provide a comprehensive review of the proposed research, the informed consent document and process are often lengthy, complex, and burdensome.2 Consequently, research participants who sign or verbalize consent often do so without truly understanding the form that they are being asked to sign. In a recent systematic review, participants in one-third of trials assessed did not have adequate understanding in the areas of risks, benefits, randomization, study aims, withdrawal, and voluntarism.3 There are no clear standards for "how much" understanding is adequate. Furthermore, we know that lower education levels, lower literacy, and a participant's primary language are all associated with poor comprehension of the informed consent process.4 These issues are particularly important when studies are being done in children, adding an additional dimension to vulnerable populations….

Vaccination, Underlying Comorbidities, and Risk of Invasive Pneumococcal Disease

Inci Yildirim, MD, MSca,b, Kimberly M. Shea, DSc, MPHa,b, Brent A. Little, PhDa, Amy L. Silverio, MAa, and Stephen I. Pelton, MDa,b on behalf of the Members of the Massachusetts Department of Public Health
Author Affiliations
aSection of Pediatric Infectious Diseases, Boston University Medical Center, Boston, Massachusetts; and
bDepartment of Epidemiology, Boston University, School of Public Health, Boston, Massachusetts

Abstract

OBJECTIVES: Children with underlying conditions remain at increased risk for invasive pneumococcal diseases (IPD). This study describes the epidemiology, serotype distribution, clinical presentations, and outcomes of IPD in children with and without comorbidity.
METHODS: Cases of childhood IPD in Massachusetts were identified via enhanced surveillance from 2002 through 2014. Demographic and clinical data were collected via follow-up telephone

interviews with parents and/or primary care providers. Underlying conditions were classified according to the 2012 Report of the Committee on Infectious Diseases and 2013 recommendations by the Advisory Committee on Immunization Practices.
RESULTS: Among 1052 IPD cases in Massachusetts children <18 years old, 22.1% had at least 1 comorbidity. Immunocompromising conditions (32.7%) and chronic respiratory diseases (22.4%) were most common. Children with comorbidities were older at the time of IPD diagnosis (median 54 vs 23 months, P < .001), had higher hospitalization (odds ratio 2.5; 95% confidence interval 1.7–3.6) and case-fatality rates (odds ratio 3.7; 95% confidence interval 1.5–8.9) compared with children without known underlying conditions after adjusting for age, gender, year of diagnosis, and pneumococcal vaccination status. During the last 2 years of the study, IPD among children with comorbidities was caused by non–pneumococcal conjugate vaccine 13 serotypes in 23-valent polysaccharide pneumococcal vaccine (6/12, 50%) or serotypes that are not included in any of the vaccines (6/12; 50%).
CONCLUSIONS: In children with comorbidity, IPD results in higher mortality, and a large proportion of disease is due to serotypes not included in current conjugate vaccines. Further research is needed, specifically to develop and evaluate additional strategies for prevention of IPD in the most vulnerable children.

Pharmaceutics
Volume 7, Issue 1 (March 2015), Pages 1-
http://www.mdpi.com/1999-4923/6/4
[No new relevant content]

Pharmacoeconomics
Volume 33, Issue 3, March 2015
http://link.springer.com/journal/40273/33/3/page/1
[No relevant content]

PLoS Currents: Outbreaks
http://currents.plos.org/outbreaks/
(Accessed 7 March 2015)
[No new relevant content]

PLoS Medicine
(Accessed 7 March 2015)
http://www.plosmedicine.org/
[No new relevant content]

PLoS Neglected Tropical Diseases
http://www.plosntds.org/
(Accessed 7 March 2015)
[No new relevant content]

PLoS One
[Accessed 7 March 2015]
http://www.plosone.org/
Pertussis Post-Exposure Prophylaxis among Household Contacts: A Cost-Utility Analysis
Nisha Thampi, Ipek Gurol-Urganci, Natasha S. Crowcroft, Beate Sander
Research Article | published 06 Mar 2015 | PLOS ONE 10.1371/journal.pone.0119271
Abstract
Background
Recent pertussis outbreaks have prompted re-examination of post-exposure prophylaxis (PEP) strategies, when immunization is not immediately protective. Chemoprophylaxis is recommended to household contacts; however there are concerns of clinical failure and significant adverse events, especially with erythromycin among infants who have the highest disease burden. Newer macrolides offer fewer side effects at higher drug costs. We sought to determine the cost-effectiveness of PEP strategies from the health care payer perspective.
Methods
A Markov model was constructed to examine 4 mutually exclusive strategies: erythromycin, azithromycin, clarithromycin, or no intervention, stratified by age group of contacts ("infant", "child", and "adult"). Transition probabilities, costs and quality-adjusted life years (QALYs) were derived from the literature. Chronic neurologic sequelae were modeled over a lifetime, with costs and QALYs discounted at 5%. Associated health outcomes and costs were compared, and incremental cost-effectiveness ratios (ICER) were calculated in 2012 Canadian dollars. Deterministic and probabilistic sensitivity analyses were performed to evaluate the degree of uncertainty in the results.
Findings
Azithromycin offered the highest QALYs in all scenarios. While this was the dominant strategy among infants, it produced an ICER of $16,963 per QALY among children and $2,415 per QALY among adults. Total QALYs with azithromycin were 19.7 for a 5-kg infant, 19.4 for a 10-year-old child, and 18.8 for a 30-year-old adult. The costs of azithromycin PEP among infants, children and adults were $1,976, $132 and $90, respectively. While results were sensitive to changes in PEP effectiveness (11% to 87%), disease transmission (variable among age groups) and hospitalization costs ($379 to $59,644), the choice of strategy remained unchanged.
Interpretation
Pertussis PEP is a cost-effective strategy compared with no intervention and plays an important role in contact management, potentially in outbreak situations. From a healthcare payer perspective, azithromycin is the optimal strategy among all contact groups

PLoS Pathogens
http://journals.plos.org/plospathogens/
(Accessed 7 March 2015)
[No new relevant content]

PNAS - Proceedings of the National Academy of Sciences of the United States of America
(Accessed 7 March 2015)

http://www.pnas.org/content/early/
[No new relevant content]

Pneumonia
Vol 6 (2015)
https://pneumonia.org.au/index.php/pneumonia/issue/current
[Reviewed earlier]

Proceedings of the Royal Society B
07 March 2015; volume 282, issue 1802
http://rspb.royalsocietypublishing.org/content/282/1802?current=y
[No relevant content]

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
April 2015; 25 (4)
http://qhr.sagepub.com/content/current
Special Issue: Perceptions of Caregivers
[No relevant content]

Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH)
December 2014 Vol. 36, No. 6
http://www.paho.org/journal/index.php?option=com_content&view=article&id=151&Itemid=266&lang=en
[Reviewed earlier]

Risk Analysis
January 2015 Volume 35, Issue 1 Pages 1–177
http://onlinelibrary.wiley.com/doi/10.1111/risa.2015.35.issue-1/issuetoc
[Reviewed earlier]

Science
6 March 2015 vol 347, issue 6226, pages 1041-1168
http://www.sciencemag.org/current.dtl
Perspective

Infectious Disease

A sustainable model for antibiotics

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AstraZeneca Innovative Medicines and Early Development, Gatehouse Drive, Waltham, MA 02451, USA.

Despite the alarming increase in the prevalence of drug-resistant bacterial infections, far fewer new antibiotics have been approved in the past decade than at the peak in the 1980s (1). The situation is particularly alarming for serious infections by Gram-negative bacteria, some of which are becoming untreatable by modern antibiotics (2–4). Particularly in low- and middle-income countries, untreatable infections are becoming an everyday reality in hospital and care settings (5). Increasing recognition of this problem is spurring a number of public and private initiatives on both sides of the Atlantic (6–8). To more effectively counter the threat of emerging resistance, we must increase the number of innovative new antibiotics in development and harness advances in diagnostic technology to preserve their efficacy.

Perspective

Infectious Disease

A return to the pre-antimicrobial era?

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2Centre for Tropical Medicine, Oxford University, Oxford, UK.
3London School of Hygiene and Tropical Medicine, London, UK.

After many years out of the limelight, antimicrobial resistance (AMR) in bacteria is firmly back on the international political and scientific agenda (1, 2). The potential impact of AMR on hospital-acquired bacterial infections such as Staphylococcus aureus and Acinetobacter baumannii in higher-income countries has created both fear and a surge of motivation aimed at providing new solutions for the problem (3, 4). The political will and momentum to tackle AMR lies in higher-income countries, but the medical, social, and economic effects of AMR are likely to be felt more in lower-income countries, particularly those in South and Southeast Asia and in sub-Saharan Africa. The identification and development of new drugs is a potential solution but is challenging and costly; any novel therapies introduced into low-income settings without a suitable infrastructure to understand and prevent the rapid development of resistance will likely be expensive and futile.

Social Science & Medicine

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

Tropical Medicine and Health

Vol. 43(2015) No. 1
https://www.jstage.jst.go.jp/browse/tmh/43/0/_contents
[Reviewed earlier]

Tropical Medicine & International Health
March 2015 Volume 20, Issue 3 Pages 251–406
http://onlinelibrary.wiley.com/doi/10.1111/tmi.2014.20.issue-1/issuetoc
[Reviewed earlier]

Vaccine
Volume 33, Issue 12, Pages 1419-1506 (17 March 2015)
http://www.sciencedirect.com/science/journal/0264410X/33/12
Discussion
Should close contacts of returning travellers with typhoid fever be protected by vaccination?
Pages 1419-1421
A. Kantele
Abstract
Increasing international travel to areas endemic for typhoid fever correlates with increased risk for travellers to contract the disease. At home, the acutely ill/convalescent patients may pose some risk to their close contacts. In Finland an unofficial guideline suggests vaccination for close contacts of patients with acute typhoid fever; in other developed countries, routine typhoid vaccinations are only recommended to contacts of chronic carriers. This paper discusses the possibilities and limitations of prophylactic/post-exposure typhoid vaccination for contacts of patients with acute disease.
Brief report
Greater freedom of speech on Web 2.0 correlates with dominance of views linking vaccines to autism
Pages 1422-1425
Anand Venkatraman, Neetika Garg, Nilay Kumar
Abstract
Introduction
It is suspected that Web 2.0 web sites, with a lot of user-generated content, often support viewpoints that link autism to vaccines.
Methods
We assessed the prevalence of the views supporting a link between vaccines and autism online by comparing YouTube, Google and Wikipedia with PubMed. Freedom of speech is highest on YouTube and progressively decreases for the others.
Results
Support for a link between vaccines and autism is most prominent on YouTube, followed by Google search results. It is far lower on Wikipedia and PubMed. Anti-vaccine activists use scientific arguments, certified physicians and official-sounding titles to gain credibility, while also leaning on celebrity endorsement and personalized stories.
Conclusions
Online communities with greater freedom of speech lead to a dominance of anti-vaccine voices. Moderation of content by editors can offer balance between free expression and factual accuracy. Health communicators and medical institutions need to step up their activity on the Internet.
Review

Comparing vaccines: A systematic review of the use of the non-inferiority margin in vaccine trials

Review Article
Pages 1426-1432
R. Donken, H.E. de Melker, N.Y. Rots, G. Berbers, M.J. Knol
Abstract
Background
Non-inferiority (NI) randomized controlled trials (RCTs) aim to demonstrate that a new treatment is no worse than a comparator that has already shown its efficacy over placebo within a pre-specified margin. However, clear guidelines on how the NI margin should be determined are lacking for vaccine trials. A difference (seroprevalence/risk) of 10% or a geometric mean titre/concentration (GMT) ratio of 1.5 or 2.0 in antibody levels is implicitly recommended for vaccine trials. We aimed to explore which NI margins were used in vaccine RCTs and how they were determined.
Methods
A systematic search for NI vaccine RCTs yielded 177 eligible articles. Data were extracted from these articles using a standardized form and included general characteristics and characteristics specific for NI trials. Relations between the study characteristics and the NI margin used were explored.
Results
Among the 143 studies using an NI margin based on difference (n = 136 on immunogenicity, n = 2 on efficacy and n = 5 on safety), 66% used a margin of 10%, 23% used margins lower than 10% (range 1–7.5%) and 11% used margins larger than 10% (range 11.5–25%). Of the 103 studies using a NI margin based on the GMT ratio, 50% used a margin of 0.67/1.5 and 49% used 0.5/2.0. As observed, 85% of the studies did not discuss the method of margin determination; and 19% of the studies lacked a confidence interval or p-value for non-inferiority.
Conclusion
Most NI vaccine RCTs used an NI margin of 10% for difference or a GMT ratio of 1.5 or 2.0 without a clear rationale. Most articles presented enough information for the reader to make a judgement about the NI margin used and the conclusions. The reporting on the design, margins used and results of NI vaccine trials could be improved; more explicit guidelines may help to achieve this end.

Modeling the durability of ZOSTAVAX® vaccine efficacy in people ≥60 years of age

Original Research Article
Pages 1499-1505
Xiaoming Li, Jane H. Zhang, Robert F. Betts, Vicki A. Morrison, Ruifeng Xu, Robbin F. Itzler, Camilo J. Acosta, Erik J. Dasbach, James M. Pellissier, Gary R. Johnson, Ivan S.F. Chan
Abstract
Since 2006, the vaccine, ZOSTAVAX®, has been licensed to prevent herpes zoster. Only limited clinical follow-up data are available to evaluate duration of protection, an important consideration when developing HZ vaccination policy recommendations. Four Poisson regression models were developed based on an integrated analysis of data from the Shingles Prevention Study and its Short Term Persistence extension to estimate the effects of years-since-vaccination and chronological-age on vaccine efficacy among people ≥60 years old. The models included number of HZ cases parsed into categories by chronological-age and time-since-vaccination as the dependent variable with different explanatory variables in each model. In all models, the interaction between vaccine-group and chronological-age was statistically

significant indicating that vaccine efficacy decreases with the expected effects of advancing age but the interaction between vaccine-group and time-since-vaccination was not statistically significant indicating that much of the reduction in vaccine efficacy over time-since-vaccination can be explained by increasing age.

Vaccines — Open Access Journal
(Accessed 7 March 2015)
http://www.mdpi.com/journal/vaccines
Review:
Choice and Design of Adjuvants for Parenteral and Mucosal Vaccines
by Huub F. J. Savelkoul, Valerie A. Ferro, Marius M. Strioga and Virgil E. J. C. Schijns
Vaccines 2015, 3 (1), 148-171; doi:10.3390/vaccines3010148 - published 5 March 2015
Abstract
The existence of pathogens that escape recognition by specific vaccines, the need to improve existing vaccines and the increased availability of therapeutic (non-infectious disease) vaccines necessitate the rational development of novel vaccine concepts based on the induction of protective cell-mediated immune responses. For naive T-cell activation, several signals resulting from innate and adaptive interactions need to be integrated, and adjuvants may interfere with some or all of these signals. Adjuvants, for example, are used to promote the immunogenicity of antigens in vaccines, by inducing a pro-inflammatory environment that enables the recruitment and promotion of the infiltration of phagocytic cells, particularly antigen-presenting cells (APC), to the injection site. Adjuvants can enhance antigen presentation, induce cytokine expression, activate APC and modulate more downstream adaptive immune reactions (vaccine delivery systems, facilitating immune Signal 1). In addition, adjuvants can act as immunopotentiators (facilitating Signals 2 and 3) exhibiting immune stimulatory effects during antigen presentation by inducing the expression of co-stimulatory molecules on APC. Together, these signals determine the strength of activation of specific T-cells, thereby also influencing the quality of the downstream T helper cytokine profiles and the differentiation of antigen-specific T helper populations (Signal 3). New adjuvants should also target specific (innate) immune cells in order to facilitate proper activation of downstream adaptive immune responses and homing (Signal 4). It is desirable that these adjuvants should be able to exert such responses in the context of mucosal administered vaccines. This review focuses on the understanding of the potential working mechanisms of the most well-known classes of adjuvants to be used effectively in vaccines.

Value in Health
January 2015 Volume 18, Issue 1, p1-136
http://www.valueinhealthjournal.com/current
[Reviewed earlier]

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

Health Education Journal
February 23, 2015 0017896915572705
Beliefs and knowledge about the human papillomavirus vaccine among undergraduate men
Theresa Hunter, Melissa Weinstein
Department of Applied Health Science, School of Public Health, Indiana University Bloomington, Bloomington, IN, USA
Abstract
Objective: The objective of this study was to assess male undergraduate students' human papillomavirus (HPV) knowledge and intentions to receive the HPV vaccination.
Design: Cross-sectional survey.
Method: A sample of 116 male undergraduate students from a university in the Midwestern USA completed a survey questionnaire assessing various aspects related to their attitudes towards the HPV vaccine.
Results: Results show that awareness and levels of knowledge about HPV and the HPV vaccine were low among male undergraduate students. The study also found that intentions to receive the HPV vaccine were very low among this population.
Conclusion: The results of this study should encourage the developmental and implementation of campus-wide health education programmes which discuss the HPV vaccine and benefits for men.

Disaster Medicine and Public Health Preparedness
Volume 9 - Issue 01 - February 2015
http://journals.cambridge.org/action/displayIssue?jid=DMP&tab=currentissue
Ebola Special Section
Ebola Virus and Public Health (Part 1)
preview
pp 29 - 29
DOI: http://dx.doi.org/10.1017/dmp.2015.18 (About DOI), Published online: 04 March 2015
Abstract
Introduction
Ebola Virus and Public Health
preview
Charles W. Beadling, Frederick M. Burkle, Jr, Kristi L. Koenig and Trueman W. Sharp
pp 31 - 31
DOI: http://dx.doi.org/10.1017/dmp.2015.16 (About DOI), Published online: 04 March 2015
Abstract
Editorial
The Ebola Epidemic and Translational Public Health
preview
James J. James
pp 32 - 32
DOI: http://dx.doi.org/10.1017/dmp.2014.106 (About DOI), Published online: 07 October 2014
Abstract
Special Reports
A Primer on Ebola for Clinicians
preview

Eric Toner, Amesh Adalja and Thomas Inglesby
pp 33 - 37
DOI: http://dx.doi.org/10.1017/dmp.2014.115 (About DOI), Published online: 17 October 2014
Abstract
Triage Management, Survival, and the Law in the Age of Ebola
preview
Frederick M Burkle, Jr and Christopher M Burkle
pp 38 - 43
DOI: http://dx.doi.org/10.1017/dmp.2014.117 (About DOI), Published online: 24 October 2014
Abstract
Commentaries
Operationalizing Public Health Skills to Resource Poor Settings: Is This the Achilles Heel in the Ebola Epidemic Campaign?
preview
Frederick M. Burkle, Jr
pp 44 - 46
DOI: http://dx.doi.org/10.1017/dmp.2014.95 (About DOI), Published online: 07 October 2014
Abstract
Global and Domestic Legal Preparedness and Response: 2014 Ebola Outbreak
preview
James G. Hodge, Jr
pp 47 - 50
DOI: http://dx.doi.org/10.1017/dmp.2014.96 (About DOI), Published online: 10 October 2014
Abstract
Hubris: The Recurring Pandemic
preview
Tom Koch
pp 51 - 56
DOI: http://dx.doi.org/10.1017/dmp.2014.107 (About DOI), Published online: 22 October 2014
Abstract
Ebola Triage Screening and Public Health: The New "Vital Sign Zero"
preview
Kristi L. Koenig
pp 57 - 58
DOI: http://dx.doi.org/10.1017/dmp.2014.120 (About DOI), Published online: 29 October 2014
Abstract
Journalists and Public Health Professionals: Challenges of a Symbiotic Relationship
preview
Pauline Lubens
pp 59 - 63
DOI: http://dx.doi.org/10.1017/dmp.2014.127 (About DOI), Published online: 10 November 2014
Abstract
The Ebola Threat: China's Response to the West African Epidemic and National Development of Prevention and Control Policies and Infrastructure
preview
Hao-Jun Fan, Hong-Wei Gao, Hui Ding, Bi-Ke Zhang and Shi-Ke Hou
pp 64 - 65

DOI: http://dx.doi.org/10.1017/dmp.2014.152 (About DOI), Published online: 07 January 2015
Abstract
Mapping Medical Disasters: Ebola Makes Old Lessons, New
preview
Tom Koch
pp 66 - 73
DOI: http://dx.doi.org/10.1017/dmp.2015.14 (About DOI), Published online: 09 February 2015
Abstract
Brief Reports
Ebola Virus Disease: Preparedness in Japan
preview
Yugo Ashino, Haorile Chagan-Yasutan, Shinichi Egawa and Toshio Hattori
pp 74 - 78
DOI: http://dx.doi.org/10.1017/dmp.2014.130 (About DOI), Published online: 17 November 2014
Abstract
Favipiravir: A New Medication for the Ebola Virus Disease Pandemic
preview
Takashi Nagata, Alan K. Lefor, Manabu Hasegawa and Masami Ishii
pp 79 - 81
DOI: http://dx.doi.org/10.1017/dmp.2014.151 (About DOI), Published online: 29 December 2014
Abstract
Concepts in Disaster Medicine
Ebola Outbreak Response: The Role of Information Resources and the National Library of Medicine
preview
Cynthia B. Love, Stacey J. Arnesen and Steven J. Phillips
pp 82 - 85
DOI: http://dx.doi.org/10.1017/dmp.2014.108 (About DOI), Published online: 17 October 2014
Abstract
Sign Me Up: Rules of the Road for Humanitarian Volunteers During the Ebola Outbreak
preview
Ryan Wildes, Stephanie Kayden, Eric Goralnick, Michelle Niescierenko, Miriam Aschkenasy, Katherine M. Kemen, Michael Vanrooyen, Paul Biddinger and Hilarie Cranmer

Intervention – Journal of Mental Health and Psychological Support in Conflict Affected Areas
March 2015 - Volume 13 - Issue 1 pp: 1-102
http://journals.lww.com/interventionjnl/pages/currenttoc.aspx
New Frontiers issue of Intervention
Articles
Surviving juntas (together): lessons of resilience of indigenous Quechua women in the aftermath of conflict in Peru
Suarez, Eliana Barrios
Measuring suffering: assessing chronic stress through hair cortisol measurement in humanitarian settings

Cunningham, Tim
Special Section
Ebola: reflections from the field
Introduction to the Special Section on Ebola: reflections from the field
Tankink, Marian
Personal reflections
Mental health and psychosocial support in the face of Ebola in Liberia: the personal and professional intersect. A personal account
Cooper, Janice L.
The travellers dance: how Ebola prevention measures affect day to day life
Gonzalez, Teresa
Field reports
Mental illness and health in Sierra Leone affected by Ebola: lessons for health workers
Hughes, Peter
An outbreak of fear, rumours and stigma: psychosocial support for the Ebola Virus Disease outbreak in West Africa
Cheung, Eliza Y.L.
Psychosocial support during the Ebola outbreak in Kailahun, Sierra Leone
Garoff, Ferdinand
How to eat an elephant: psychosocial support during an Ebola outbreak in Sierra Leone
Jónasdóttir, Elín
Announcement
Reaching out a helping hand during Ebola: adaptation of the Psychological First Aid guide

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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://america.aljazeera.com/search.html?q=vaccine
Accessed 7 March 2015
[No new, unique, relevant content]

The Atlantic

http://www.theatlantic.com/magazine/
Accessed 7 March 201
[No new, unique, relevant content]

BBC
http://www.bbc.co.uk/
Accessed 7 March 2015
[No new, unique, relevant content]

Brookings
http://www.brookings.edu/
Accessed 7 March 2015
[No new, unique, relevant content]

Council on Foreign Relations
http://www.cfr.org/
Accessed 7 March 2015
[No new, unique, relevant content]

The Economist
http://www.economist.com/
Accessed 7 March 2015
[No new, unique, relevant content]

Financial Times
http://www.ft.com/home/uk
Accessed 7 March 2015
[No new, unique, relevant content]

Forbes
http://www.forbes.com/
Accessed 7 March 2015
[No new, unique, relevant content]

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 7 March 2015
[No new, unique, relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 7 March 2015
[No new, unique, relevant content]

The Huffington Post
http://www.huffingtonpost.com/
How We Can End the Anti-vaccination Feud
5 March 2015

by John Hewko, General secretary of Rotary International

It is time to move beyond the blame game regarding childhood vaccinations and replace it with honest dialogue and outreach in order to ensure the current measles outbreak -- which has infected more than 170 people in 17 states -- doesn't happen again. This follows a record 644 cases in 2014, the highest caseload since the U.S. Centers for Disease Control and Prevention declared that measles had been eliminated in our country in 2000.

Continuing the current tone of confrontation will only aggravate the growing schism between those who refuse vaccinations and those of us who believe vaccines are the public's best defense against communicable diseases. The real public health solution is to identify common ground and talk to each other…

Mail & Guardian
http://mg.co.za/
Accessed 7 March 2015
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 7 March 2015
[No new, unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 7 March 2015
Last Known Ebola Patient in Liberia Is Discharged
5 March 2015

Liberia's last Ebola patient was discharged on Thursday after a ceremony in the capital, Monrovia, bringing to zero the number of known cases in the country and marking a milestone in West Africa's battle against the disease. Officials in Monrovia, the city where the raging epidemic littered the streets with bodies only five months ago, celebrated even as they warned that Liberia was at least weeks away from being officially declared free of Ebola. They also noted that the disease had flared up recently in neighboring Sierra Leone and Guinea, the two other countries hardest hit by it…

Wall Street Journal
http://online.wsj.com/home-page?_wsjregion=na,us&_homepage=/home/us
Accessed 7 March 2015
Virulent Flu Strain in Europe Hits Economy
Europe's convalescent economy faces a new burden: an unusually virulent strain of flu that is shutting down schools, stopping commuter trains, and keeping workers and consumers in bed. In Germany, the cost of the epidemic could reach $2.4 billion, according to an economic institute.
Yesterday 11:51:00 AM

Washington Post
http://www.washingtonpost.com/
Accessed 7 March 2015
[No new, unique, relevant content]

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Support for this service is provided by its governing institutions – Department of Medical Ethics, NYU Medical School; The Wistar Institute Vaccine Center and the Children's Hospital of Philadelphia Vaccine Education Center. Additional support is provided by the PATH Vaccine Development Program; the International Vaccine Institute (IVI); the Bill & Melinda Gates 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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