Center for Vaccine Ethics and Policy
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Vaccines and Global Health: The Week in Review
21 June 2014
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: 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 3,500 entries.

Comments and suggestions should be directed to
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WHO: Humanitarian Health Action [to 21 June 2014]
http://www.who.int/hac/en/

WHO responds to deteriorating humanitarian situation in Iraq
16 June, 2014
Excerpt; Editor's text bolding

WHO is working with local and international partners in Iraq to meet the urgent health needs of populations affected by the ongoing crisis.

The humanitarian situation in Iraq has deteriorated dramatically in the last few days, especially in the regions of Ninewa, Salaheddin and Diyala provinces. More than 500 000 people are estimated to have fled their homes in Mosul and surrounding areas. An estimated 100 000 have entered Erbil and 200 000 have fled to Dohuk. Almost 25 000 are seeking shelter in schools and mosques in Mosul City, many with no access to drinking- water, as the main water station for the area was destroyed by bombing, and food shortages are being reported. As the fighting continues, hundreds of thousands more are stranded at checkpoints with no belongings or money for housing, food, water or medical care. Accurate figures of casualties are unavailable but stand in the hundreds.

WHO is concerned about the health situation, which is expected to deteriorate given increasing numbers of people requiring humanitarian assistance and the difficulties faced in channelling human resources and logistics from Baghdad to affected areas.

Immediate and critical health risks of concern to WHO include the spread of measles, which is endemic in Mosul and could potentially lead to outbreaks, especially in overcrowded areas where internally-displaced persons are located. The spread of polio is also a high risk as new cases were reported in the country earlier this year as a result of the Syria crisis.

To monitor disease outbreaks, WHO has strengthened its disease early warning alert and response system in Kurdistan and Mosul. WHO is also launching emergency polio and measles vaccination activities for internally-displaced persons with the directorates of health in Dohuk and Erbil….

UNICEF Watch [to 21 June 2014]
http://www.unicef.org/media/media_71724.html

UNICEF and partners vaccinating over 1.1 million people in Guinea to halt meningitis outbreak

CONAKRY, Guinea, 16 June 2014 – This weekend, the Government of Guinea, the World Health Organization, and UNICEF completed a vaccination campaign in the country's Eastern Region where a recent meningitis outbreak has already caused at least 52 deaths since the beginning of the year.

WHO statement on the Sixth Meeting of the IHR Emergency Committee concerning MERS-CoV

WHO statement
17 June 2014
Excerpt; Editor's bold text

The sixth meeting of the Emergency Committee convened by the Director-General under the International Health Regulations (2005) concerning Middle East respiratory syndrome coronavirus (MERS-CoV) was held by teleconference on Monday, 16 June 2014, from 12:15 to 16:19 Geneva time (CEST).

Seven affected States Parties reporting cases of MERS-CoV or evidence of infection since the fifth meeting of the Committee were also on the first part of the teleconference: Algeria, Iran, Jordan, Netherlands, Saudi Arabia, United Arab Emirates (UAE), and United States of America.

The WHO Secretariat provided an update on and assessment of epidemiological and scientific developments, including a description of recently reported cases, transmission patterns, and the main observations of a recent WHO mission to UAE.

Affected countries gave information about recent events in their countries, including description of cases, measures taken and their concerns about the current situation.

The Committee discussed the information provided. Based on current information, the Committee indicated that the situation remains serious in terms of public health impact. However, the upsurge in cases that began in April has now decreased and there is no evidence of sustained human-to-human transmission in communities. There have been significant efforts made to strengthen infection prevention and control measures. As a result, **the Committee unanimously concluded that the conditions for a Public Health Emergency of International Concern (PHEIC) have not yet been met.**

However, the Committee emphasized that the situation continues to be of concern, especially given the anticipated increase in travel to Saudi Arabia related to Umra, Ramadan and the Hajj. The Committee focused attention on the need to further analyse the

hospital outbreaks to better understand where breaches in infection prevention and control are taking place, including where patients who have not yet received a diagnosis gather and wait, often under crowded conditions, such as in emergency departments and clinics. The Committee also noted that recent investigative findings increasingly support the hypothesis that camels are an important source of exposure to MERS-CoV in the community…

Nature | Editorial

Present danger

There is much hype about predicting and preventing future pandemics, but not enough is being done about a threat sitting under our noses.

Nature, Volume 510 Number 7505 pp312-436 19 June 2014

[Full text]

If the deadly disease MERS-CoV evolves to spread easily between humans and cause a global outbreak, hard questions will be asked. Why did health authorities and scientists allow a virus with clear pandemic potential to fester for so long, and what more could have been done to nip it in the bud? Those questions need to be asked now, when there is still time to deal with the crisis.

As of 16 June, the World Health Organization (WHO) had reported 701 lab-confirmed cases of MERS-CoV (Middle East respiratory syndrome coronavirus), including 249 deaths, since the virus was first identified in September 2012. The reported cases are largely confined to the Middle East, with most in Saudi Arabia.

MERS-CoV is, in principle, eminently stoppable. It remains an animal-borne virus that sporadically infects humans: there have been large hospital outbreaks in which patients have infected health-care workers and others, but so far the virus does not spread easily between people. By tracking down its animal sources and the routes through which people contract it, authorities should be able to dam the stream of infections.

But there is a risk that MERS-CoV, like the coronavirus SARS (severe acute respiratory syndrome), might mutate to spread easily between humans and so propagate rapidly around the world. SARS was detected in late 2002 and stamped out in July 2003; in those few months, it caused more than 8,000 infections and 700 deaths. Key to the defeat of SARS was a tightly coordinated international public-health effort, led by the WHO. The organization assembled an effective in-house outbreak-response team and quickly put together an international network of scientists that for the most part set competition aside in favour of collaboration.

Partly as a result of SARS, in 2005 the WHO's member states agreed on legally binding International Health Regulations to strengthen the international response to public-health events that occur in individual countries but potentially pose a global threat. The rules, for example, require countries to strengthen their disease surveillance and outbreak-response infrastructure, and to report all cases of possible international concern to the WHO within 24 hours.

Try harder

When it comes to MERS-CoV, the lessons of SARS success have too often been ignored. This is perhaps due in part to a mistaken perception that MERS-CoV is less urgent than was SARS, because it does not yet spread easily between people. Research groups have tended to compete rather than cooperate. From the outset, conflict and distrust over credit, patents and sharing of specimens and data have marred efforts (see Nature http://doi.org/s75; 2013).

Saudi Arabia's response to MERS-CoV has been better than many of its critics give it credit for. Tackling the outbreak is challenging: with only a few hundred cases to go on, tracking down clues to the source of infections is not easy in a country that is almost three and a half

times the size of France. But even so, response efforts have suffered from ineptitude, infighting and inadequate transparency. Saudi Arabia may be rich, but it is on a steep learning curve when it comes to international research collaboration and dealing with a complicated outbreak. "Diplomacy and trust are key to building an effective outbreak response."

In April, Saudi Arabia replaced its health minister as case numbers surged, and last month it created a Command and Control Center that brings together scientists and public-health officials to better coordinate control efforts, and acts as a focal point for international collaboration. This month, it removed deputy health minister Ziad Memish — the most prominent public face of Saudi MERS-CoV efforts — and announced 113 cases and 92 deaths that had occurred since 2012 but had gone unreported (these cases are not included in the WHO's latest totals). It is too soon to say how effective the Command and Control Center will be, but domestic pressure to stop MERS-CoV is at an all-time high.

The WHO has been much less prominent and decisive on MERS-CoV than it was on SARS. Its outbreak-response division is underfunded and understaffed, and effective leadership has been lacking.

On the positive side, researchers have obtained a lead, finding the virus in camels in Saudi Arabia, Egypt, Oman and Qatar. Antibodies to the pathogen — evidence of past infection — have been detected in camels in many countries in the Middle East and North Africa. Last week, researchers reported finding the virus in unpasteurized camel milk. But almost two years after MERS-CoV was first identified, no one has definitively pinned down its routes of transmission to humans. Scientists and authorities could, and should, do better.

The many cases caused by hospital outbreaks, for instance, could have been prevented by rigorous infection-control measures. Rapid identification and isolation of cases, decontamination of surfaces and use of protective clothing such as masks can all help to block infection of people in contact with patients.

Outbreak response cannot always be decreed by international rules. There is tension between the sovereign right of nations to handle the situation in their own countries and the desire of the international community to intervene and prevent the disease crossing borders. Diplomacy and trust are key to building an effective outbreak response. Saudi Arabia needs to be encouraged, not alienated.

The International Health Regulations say little about research, but a separate WHO agreement sets out clear rules for sharing samples and sequences of pandemic influenza viruses. Similar rules for all infectious diseases that have pandemic potential are needed.

What is most lacking in the fight against MERS-CoV is global leadership. The WHO, as an intergovernmental agency with a direct line to health ministries, remains best placed to bang heads together and get things done cooperatively, but its efforts must be well funded and staffed. Politicians everywhere must wake up to the fact that the world has another Middle East problem.

POLIO [to 21 June 2014]
GPEI Update: Polio this week - *As of 18 June 2014*
Global Polio Eradication Initiative
Editor's Excerpt and text bolding
Full report: http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx
:: At an International Ulema Conference on Polio Eradication organized by the Islamic Development Bank, leading Islamic scholars called for the entire Muslim world to unite in

eradicating polio, and declared the polio vaccination as a parental and community responsibility. The scholars were convened from Pakistan, Saudi Arabia, Egypt, Afghanistan and Nigeria.
:: The Global Polio Partners Group (PPG) met on Monday 16 June in Geneva to review the development and implementation of short-term and long-term polio eradication strategic plans and emergency action plans. Speakers' presentations from the PPG meeting are available here *[see below].*

Afghanistan

:: Two new WPV1 cases were reported in the past week from previously uninfected areas including a case from Achin district, Nangarhar province, with onset of paralysis on 15 May, and a case from Dehrawud, Uruzgan province, with onset of paralysis on 20 May, bringing the total number of WPV1 cases for 2014 to six. Targeted mop-up campaigns are starting this Sunday in the areas where the two cases were found, followed by sub-national campaigns in Uruzgan as well as in targeted districts in Kandahar province and in Northern Helmand province…

Pakistan

:: Seven new WPV1 cases were reported in the past week from the Federally Administered Tribal Areas – FATA including five cases from North Waziristan and two cases from Khyber agency. The most recent WPV1 case had onset of paralysis on 4 June from Khyber agency. The total number of WPV1 cases reported from Pakistan for 2014 is 82…

Global Polio Partners Group (PPG) Meeting: 16 June 2014

The Polio Partners Group serves as the stakeholder voice for the Global Polio Eradication Initiative (GPEI) in the development and implementation of short-term and long-term polio eradication strategic plans and emergency action plans. The PPG also fosters greater engagement among polio-affected countries, donors and other partners with the objective of utilizing their political, communications, programmatic and financial capabilities to ensure GPEI has the necessary political commitment and financial resources to reach the goal of polio eradication.

The PPG meets in-person at least two times per year at the ambassadorial/senior-officials level, with the possibility of holding additional ad-hoc conference calls or meetings. Results are reported to the GPEI Polio Oversight Board. Terms of Reference

Presentations

1. Overview – Interrupting Polio Transmission (Dr B. Aylward)
2. Communications and mobilization (S. Guirguis)
3. Progress with IPV introduction (M. Zaffran)
4. Polio Legacy Planning (A. Freeman)
5. Financial and Budget update (J. Linkins)
6. Monitoring Framework (A. Freeman)

High-level Delegation Reaffirms Commitment to Strengthen Polio Eradication Support to Doollo Zone, Somali Region

WHO AFRO

Excerpt

Warder. 21 June 2014 – High-level officials from the Federal Ministry of Health, Somali Regional State, WHO and UNICEF visited Warder, the epicentre of the wild polio virus outbreak in Ethiopia, on 21 June 2014 and assured to strengthen support to Doollo Zone, Somali Region, to accelerate progress towards polio eradication…

…The delegation launched, together with the Zonal Administration, the ninth round of polio supplementary immunization activities (SIAs) in the outbreak zone, which will be running from

14 to 18 June 2014.

The high-level officials formally inaugurated the Zonal Polio Outbreak Command Post, which had been established in April 2014 to improve coordination of response activities. The delegation received a briefing on the current status of the response from Dr Hassan Sugulle, WHO Polio Consultant, based in Doollo zone, who emphasized the need to do more to reach nomadic communities…

…On behalf of all partners – WHO, UNICEF, Bill and Melinda Gates Foundation, USAID, CDC, CORE GROUP, DFID, GAVI Alliance, Rotary International and MSF – Dr Pierre M'Pele-Kilebou, WHO Representative, acknowledged the strong commitment and progress made in Doollo Zone. He reaffirmed the support of all EPI partners and committed their support to overcome the remaining challenges in reaching every child in Doollo Zone and to prevent further transmission of wild polio virus in Ethiopia.

Battling polio: IDPs turned back at Pak-Afghan border for refusing vaccine
By Sehrish Wasif
The Express Tribune with the International New York Times (Pakistan) (6/20)
Published: June 20, 2014
Excerpt
ISLAMABAD:
Nearly 40 trucks carrying internally displaced persons (IDPs) from North Waziristan en route to Afghanistan were turned back by the Pakistan army at the Pak-Afghan border on Thursday.

Speaking with The Express Tribune, an official said the families had refused to have their children vaccinated against polio. "They have demanded that the government should first provide them with proper food and shelter before they have their children vaccinated," the official said on the condition of anonymity. The trucks were diverted to a camp in Bannu.

The official said that it is now the provincial government's responsibility to ensure that all IDPs entering the province are vaccinated against polio. Military officials told The Express Tribune that they hope Operation Zarb-e-Azb will enable access to children who have not received the vaccine since 2012. Vaccinations will be carried out at check posts and 20 registration centres – with ten each for men and women – have been set up, military sources said….

WHO: Global Alert and Response (GAR) – *Disease Outbreak News* [to 21 June 2014]
http://www.who.int/csr/don/en/
:: **Human infection with avian influenza A(H7N9) virus – update 18 June 2014**
:: **Ebola virus disease, West Africa – update 18 June 2014**
Excerpt

…Following the confirmation of new cases and deaths in new areas in Guinea, Liberia, and Sierra Leone, WHO and its partners continue to provide the necessary technical expertise to the Ministries of Health to stop community and health facility transmission of the virus. A high-level WHO mission was conducted in Guinea to assess the overall response to EVD and propose a strategic approach to control the outbreak. Among other actions, this includes high-level advocacy with the Governments of the three affected countries to enhance coordination and communication at all national, provincial, and district levels.

WHO is also closely supporting the Ministries of Health in addressing community resistance that is emerging in some areas; deploying additional experts in the various specialities (epidemiology, social mobilization, case management, and logistics among

others); and enhancing cross-border collaboration. The next cross-border meeting between the three countries is planned for 23 June 2014.

WHO does not recommend any travel or trade restrictions be applied to Guinea, Liberia, or Sierra Leone based on the current information available for this event.

:: **Middle East respiratory syndrome coronavirus (MERS-CoV) – update 16 June 2014**
:: **Middle East respiratory syndrome coronavirus (MERS-CoV) – update 21 June 2014**

The **Weekly Epidemiological Record (WER) for 20 June 2014**, vol. 89, 25 (pp. 265–288) includes:
:: Varicella and herpes zoster vaccines: WHO position paper, June 2014
http://www.who.int/entity/wer/2014/wer8925.pdf?ua=1

CDC/MMWR Watch [to 21 June 2014]
http://www.cdc.gov/mmwr/mmwr_wk.html
:: CDC Lab Determines Possible Anthrax Exposures: Staff Provided Antibiotics/Monitoring - Media Statement
June 19, 2014
CDC announced today that approximately 75 Atlanta-based staff are being monitored or provided antibiotics because they may have been unintentionally exposed to live Bacillus anthracis (anthrax) after established safety practices were not followed.
:: **MMWR, June 20, 2014** / Vol. 63 / No. 24
Use of MenACWY-CRM Vaccine in Children Aged 2 Through 23 Months at Increased Risk for Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices, 2013

GAVI Watch [to 21 June 2014]
http://www.gavialliance.org/library/news/press-releases/
:: GAVI Alliance Board approves new strategic framework to reach an additional 300 million children with vaccines
Press release: Excerpt

Geneva, 19 June 2014 – The GAVI Alliance Board today approved the strategic framework that would support a fully funded Alliance to enable developing countries to immunise an additional 300 million children between 2016 and 2020, helping to save an estimated five to six million lives.

The Alliance will consolidate the progress made over the past four years following the rapid acceleration of GAVI-supported vaccine introductions by the world's poorest countries. This has put countries on target to immunise almost a quarter of a billion children between 2011 and 2015, saving close to four million lives.

By continuing to support new vaccine introductions, increasing coverage of vaccines introduced with Alliance support and strengthening immunisation delivery, the GAVI Alliance projects that up to 50% of children in the 73 GAVI-supported countries will be receiving all 11 vaccines recommended by the World Health Organization for universal use by 2020. This compares to less than 5% today.

With more than 20 countries expected to graduate from GAVI Alliance support by the end of 2020, the strategy has a clear focus on assisting countries to develop sustainable, self-sufficient immunisation programmes.

Donors have been asked to contribute a total of US$ 7.5 billion to ensure Alliance-supported immunisation programmes are fully funded for the 2016 to 2020 period…

…The new strategic framework will bring Alliance partners together to work towards four key goals that will ensure programmes are both effective and sustainable:

:: Accelerate equitable uptake and coverage of vaccines
:: Increase effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems
:: Improve sustainability of national immunisation programmes
:: Shape markets for vaccines and other immunisation products.

In addition, the framework recognises the importance of addressing key strategic enablers for a successful 2016-2020 strategy: country leadership, management and coordination; resource mobilisation; advocacy; and monitoring and evaluation….

:: **Hepatitis B vaccine at birth – GAVI responds to MSF**

GAVI respond to Médecins Sans Frontières and civil society organisations' open letter
Excerpt

Geneva, 20 June 2014 - GAVI Alliance shares recently published MSF concerns about the slow implementation of the WHO recommendation to deliver a dose of hepatitis B vaccine immediately after birth.

WHO estimates that hepatitis B causes around 260,000 deaths each year in GAVI-eligible countries, mostly in older men. Thanks to GAVI's support for infant hepatitis B vaccination since 2000 - now included in the pentavalent vaccine and in routine use in 72 of 73 GAVI-supported countries - this number is expected to fall significantly in the future.

GAVI agrees that greater use of a birth dose of hepatitis B vaccine would be valuable in line with the WHO recommendation. Therefore, the Alliance recently re-assessed the relative value of GAVI financial support for birth dose hepatitis B vaccine as part of the new Vaccine Investment Strategy. This evaluated fifteen vaccines looking at relative value of and feasibility of GAVI support. Based on these analyses and extensive consultations, the GAVI Board decided not to pursue offering financial support for countries wishing to introduce birth dose hepatitis B vaccine. A detailed analysis is available on this page.

The key points that factored into the decision were:

:: Consultations with experts and stakeholder highlighted implementation challenges as the primary barrier to adoption, rather than price of the vaccine.
:: The cost per dose of hepB birth dose is around $0.20, which is equivalent to the minimum amount of co-financing that all GAVI-eligible countries contribute to GAVI-supported vaccines.
:: A key driver of uncertainty in estimating the impact of a possible investment in hepatitis B birth dose was the coverage that can be achieved within the narrow window of 24 hours after birth for institutional births. Many births in GAVI-eligible countries do occur outside health facilities. Indeed, coverage of hepatitis B birth dose in many countries delivering this intervention is low.

Although GAVI is not providing direct financial support for the birth dose hepatitis B vaccine, as the Investment Strategy analysis and consultations concluded that the Alliance should focus its limited resources on other high-impact vaccines, GAVI would be very pleased to discuss how we might collectively work to encourage greater use of the vaccine. GAVI would also hope that such discussions could be channelled through the CSO mechanism already established by the GAVI Board.

[Editor's Supplement: Civil society groups call on GAVI to support birth dose vaccination for hepatitis B
13 June 2014
Open letter: PDF download

Seventy six groups have co-signed MSF's letter urging the GAVI Alliance to support a hepatitis B virus (HBV) birth dose vaccination. Hepatitis B affects more than 240 million people globally, causing over 600,000 deaths each year. The highest burden of HBV infection lies in low- and middle-income countries, but only 18 of 56 GAVI-eligible countries are currently delivering the HBV birth dose.

:: **GAVI Alliance receives C$ 20 million from Canada to support immunisation supply chain strategy**

Funding aligned with Canadian PM Harper's initiative to improve maternal, newborn and child health

Excerpt

Geneva, 18 June 2014 – The GAVI Alliance has received a C$ 20 million contribution from the Canadian government to support the Alliance's immunisation supply chain strategy that will help provide more children in the world's poorest countries with access to life saving vaccines. The supply chain strategy was approved this week by the GAVI Alliance Board.

The funding is part of Canada's global leadership around maternal, newborn and child health (MNCH) – the country's top development priority – with the C$ 20 million contribution (about US$ 18.5 million) budgeted through its groundbreaking Muskoka Initiative launched in 2010.

The contribution will help improve the storage, handling and stock management of vaccines funded by the GAVI Alliance, including:

:: increasing the availability of vaccines
:: building human resource capacity to manage immunisation supply chains
:: increasing the availability and use of data on vaccine stocks…

Global Fund Watch [to 21 June 2014]
http://www.theglobalfund.org/en/mediacenter/announcements/

:: **Harley Feldbaum to Lead Policy Hub at the Global Fund**

20 June 2014

GENEVA - The Global Fund announced today that Harley Feldbaum will become Head of Strategy and Policy, a newly-created position to coordinate and oversee strategic and policy planning. Mr. Feldbaum will support the Global Fund's Board in the implementation of its overall strategy, and will work closely with the Board's Strategy Investment and Impact Committee…

European Medicines Agency Watch [to 21 June 2014]
http://www.ema.europa.eu/ema/
19/06/2014

:: **Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) to become mandatory for sponsors as of 21 July 2014**

As of 21 July 2014, it will become mandatory for sponsors to post clinical trial results in the European Clinical trials Database (EudraCT), managed by the European Medicines Agency (EMA). This date corresponds to the finalisation of the programming of the database as referred to in a European Commission guideline, in application of the current clinical trials Directive 2001/20/EC and the Paediatric Regulation. Under these frameworks, since the result-related

information is fed into the publicly accessible European Union Clinical Trials Register, summary results of clinical trials will become available to the public as sponsors start to comply with their legal obligations….

NGO Watch [to 21 June 2014]

:: **PATH receives grant to expand drug research for deadly diarrhea**

June 16, 2014—PATH announced today a three-year, US$15.6 million grant from the Bill & Melinda Gates Foundation to build a portfolio of projects with the goal of developing safe and effective treatments for severe acute secretory diarrhea (ASD). ASD, a type of diarrhea characterized by rapid onset and severe loss of water and electrolytes, causes most of the child deaths due to diarrheal disease around the world.

PATH will explore potential antisecretory drug targets in the gastrointestinal tract that are thought to play a critical role in fluid secretion, and identify existing compounds or new leads to be tested as antisecretory treatments. Such drugs will complement the use of oral rehydration therapy (ORT), the current standard of care.

"This new grant will enable PATH to expand innovation in drug development to save the lives of more children in low-income countries," said Steve Davis, PATH's president and chief executive officer. "The partnerships we create through this project will be crucial for eventually scaling up use of any new treatments we may develop for diarrheal disease."…

Industry Watch [to 21 June 2014]

Selected media releases and other selected content from industry.

:: Hilleman Laboratories announces strategic collaboration with Gotovax AB to develop next generation Oral Cholera Vaccine

Date: 17/06/2014

Aims to offer OCVs at a significantly more affordable price than the ones currently available in the market for developing countries

:: First-of-its-kind partnership undertaken to address unmet needs of the Cholera disease burden in highly endemic areas like Bengal delta, Africa

:: Demand for vaccine is expected to sharply increase in Cholera endemic countries

:: Hilleman Laboratories' thermostability technology to facilitate stockpiling in diverse geographies

Excerpt

New Delhi, June 17, 2014: Hilleman Laboratories, an equal joint-venture partnership between Merck & Co., a global research-driven pharmaceutical company and Wellcome Trust, a global charitable foundation, today announces its strategic collaboration with Gotovax AB, a University of Gothenburg spin-off biopharmaceutical company, to develop a high impact Oral Cholera Vaccine. With this collaboration, Hilleman Laboratories aims to deliver the vaccine at a significantly more affordable price than the ones currently available in the market. Easy to administer, with cross protection against ETEC diarrhea and enhanced with a longer shelf life; this vaccine candidate will be most suited for geographies with the highest cholera burden like Africa and South Asia.

"Cholera is endemic in over 50 countries with estimated mortality of 100,000-120,000 deaths and a morbidity of 3.8-4.4 million annual cases attributed to this disease. There is an urgent need of highly effective and affordable Cholera vaccines both for outbreaks as well as mass vaccination campaigns. Our partnership with Gotovax AB is carefully aligned to Hilleman

Laboratories' core philosophy of addressing unmet health needs of the underprivileged by developing accessible and innovative vaccines which are affordable," said Dr. Davinder Gill, CEO, Hilleman Laboratories…

UN Watch [to 21 June 2014]
Selected meetings, press releases, and press conferences relevant to immunization, vaccines, infectious diseases, global health, etc. http://www.un.org/en/unpress/
No new relevant 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

Meeting: Toward a Human Vaccines Project
Breaking New Ground in a Collective Search for Vaccines against Major Killer Diseases
SOURCE International AIDS Vaccine Initiative
Excerpt

NEW YORK, June 18, 2014 /PRNewswire-USNewswire/ -- New technologies and insights in antigen discovery, genomics and immunological monitoring offer tremendous potential that could be collectively leveraged to speed development of vaccines against major diseases, according to leading scientists who met across specializations to explore creation of a Human Vaccines Project and reported their conclusions in today's issue of *Nature Immunology*.

Vaccines are one of the greatest success stories in the history of public health but remain elusive for persistent global diseases such as AIDS, tuberculosis and malaria, which together kill more than 3.5 million people a year and infect millions more, despite impressive advances in treatment and prevention. Previously successful vaccine development strategies don't work against a number of today's complex parasites, bacteria, viruses and cancers.

"A Human Vaccines Project focused on solving the major scientific problems impeding vaccine development could be transformative for efforts to help prevent these devastating infectious diseases as well as certain cancers," said Wayne C. Koff, Chief Scientific Officer of the International AIDS Vaccine Initiative (IAVI) and lead author of the report.

The 35 experts from industry, academia, government and nongovernmental organizations met Feb. 5-6 in La Jolla, California, and "concluded that the concept for a Human Vaccines Project was meritorious, timely and potentially transformative," the report stated. The group identified three major common challenges in vaccine research and development: an insufficient understanding of how to generate specific, potent, broad and durable immune responses in humans; an insufficient understanding of precise antigens required to produce desired protective immunity, and a need for a deeper appreciation of how best to optimize vaccine efficacy in newborns, the elderly and populations in the developing world.

They recommended that the Human Vaccines Project focus on mapping the human immune system into a "human immunome" to facilitate vaccine discovery, and on a comprehensive

series of systematic human immunology-based clinical research studies with experimental vaccines aimed at solving the identified scientific challenges and overcoming the limited predictive powers of animal models…

…The February meeting was the first of three workshops to catalyze the Human Vaccines Project, with an initial focus on identifying key objectives to inform the project's scientific plan. The second workshop, to be held in New York City in July, will focus on organizational, management and financial questions to inform a business plan. The third workshop, projected for late 2014 or early 2015, will bring together key stakeholders and potential donors to review the scientific and business plans and prepare for a projected launch in 2015. The three initial workshops are funded by a grant to IAVI from the Robert Wood Johnson Foundation…

…"We are at a pivotal point in the history of biological and vaccine sciences, with an unprecedented opportunity to prevent some of humanity's worst diseases. A Human Vaccines Project has the potential to make that vision a reality," said report co-author Stanley Plotkin, Emeritus Professor of the University of Pennsylvania and Chairman of the Human Vaccines Project Steering Committee.

Nature Immunology
15, 589–592 (2014)
Commentary
Toward a Human Vaccines Project
Wayne C Koff, Ian D Gust & Stanley A Plotkin
Affiliations
doi:10.1038/ni.2871 Published online 18 June 2014 [not open access]

WHO report: Placebo use in vaccine trials: Recommendations of a WHO expert panel
Annette Rida, Abha Saxenab, Abdhullah H. Baquic, Anant Bhand, Julie Binese, Marie-Charlotte Bouesseauf, Arthur Caplang, James Colgroveh, Ames Dhaii, Rita Gomez-Diazj, Shane K. Greenk, Gagandeep Kangl, Rosanna Lagosm, Patricia Lohn, Alex John Londono, Kim Mulhollandp, Pieter Neelsq, Punee Pitisuttithumr, Samba Cor Sarrs, Michael Selgelidt, Mark Sheehanu, Peter G. Smithv
Vaccine
Available online 25 April 2014
In Press, Corrected Proof — Note to users
DOI: 10.1016/j.vaccine.2014.04.022

Highlights
Placebo controls may be acceptable even when an efficacious vaccine exists, in the following four possible situations:
:: When developing a locally affordable vaccine.
:: When evaluating the local safety and efficacy of an existing vaccine.
:: When testing a new vaccine when an existing vaccine is not considered appropriate locally.
:: When determining the local burden of disease.
Abstract
Vaccines are among the most cost-effective interventions against infectious diseases. Many candidate vaccines targeting neglected diseases in low- and middle-income countries are now progressing to large-scale clinical testing. However, controversy surrounds the appropriate design of vaccine trials and, in particular, the use of unvaccinated controls (with or without placebo) when an efficacious vaccine already exists. This paper specifies four situations in which placebo use may be acceptable, provided that the study question cannot be answered in

an active-controlled trial design; the risks of delaying or foregoing an efficacious vaccine are mitigated; the risks of using a placebo control are justified by the social and public health value of the research; and the research is responsive to local health needs. The four situations are: (1) developing a locally affordable vaccine, (2) evaluating the local safety and efficacy of an existing vaccine, (3) testing a new vaccine when an existing vaccine is considered inappropriate for local use (e.g. based on epidemiologic or demographic factors), and (4) determining the local burden of disease.

WHO: Position paper on varicella and herpes zoster vaccines
pdf, 889kb
20 June 2014

Report: UNHCR Global Trends 2013 – War's Human Cost
June 2013 52 pages
Overview
By end-2013, 51.2 million individuals were forcibly displaced worldwide as a result of persecution, conflict, generalized violence, or human rights violations. Some 16.7 million persons were refugees: 11.7 million under UNHCR's mandate and 5.0 million Palestinian refugees registered by UNRWA. The global figure included 33.3 million internally displaced persons (IDPs) (1) and close to 1.2 million asylum-seekers. If these 51.2 million persons were a nation, they would make up the 26th largest in the world.
[Editor's Note: the report does not address the status or challenges associated with immunization of forcibly displaced persons]

IOM Report: Supporting a Movement for Health and Health Equity - Workshop Summary
Institute of Medicine, Washington, DC
June 18, 2014; 91 pages
Overview
The idea of movements and movement building is inextricably linked with the history of public health. Historically, most movements—including, for example, those for safer working conditions, for clean water, and for safe food—have emerged from the sustained efforts of many different groups of individuals, which were often organized in order to protest and advocate for changes in the name of such values as fairness and human rights.
On December 5, 2013, the IOM Roundtable on Population Health Improvement and the Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities co-sponsored a workshop to explore the history of social movements, both those that are health-related and those that are not primarily focused on health. The objective was to learn and discuss lessons that may be applied by those who are working to improve health and health equity in U.S. communities. This document summarizes the workshop.

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 14, Issue 6, 2014
http://www.tandfonline.com/toc/uajb20/current
[Reviewed earlier]

American Journal of Infection Control
Vol 42 | No. 6 | June 2014 | Pages 585-696
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
Volume 47, Issue 1, p1-104, e1-e2 July 2014
http://www.ajpmonline.org/current

Age-Specific Strategies for Immunization Reminders and Recalls

A Registry-Based Randomized Trial

Kevin J. Dombkowski, DrPH, MS, Lauren E. Costello, MSW, Laura B. Harrington, MPH, Shiming Dong, MS, Maureen Kolasa, MPH, BSN, Sarah J. Clark, MPH

Published Online: April 18, 2014
This activity is available for CME credit. See page A3 for information.
DOI: http://dx.doi.org/10.1016/j.amepre.2014.02.009

Abstract

Background

Although previous studies have found reminder/recall to be effective in increasing immunization rates, little guidance exists regarding the specific ages at which it is optimal to send reminder/recall notices.

Purpose

To assess the relative effectiveness of centralized reminder/recall strategies targeting age-specific vaccination milestones among children in urban areas during June 2008–June 2009.

Methods

Three reminder/recall strategies used capabilities of the Michigan Care Improvement Registry (MCIR), a statewide immunization information system: a 7-month recall strategy, a 12-month reminder strategy, and a 19-month recall strategy. Eligible children were randomized to notification (intervention) or no notification groups (control). Primary study outcomes included MCIR-recorded immunization activity (administration of ≥1 new dose, entry of ≥1 historic dose, entry of immunization waiver) within 60 days following each notification cycle.

Results

A total of 10,175 children were included: 2,072 for the 7-month recall, 3,502 for the 12-month reminder, and 4,601 for the 19-month recall. Immunization activity was similar between notification versus no notification groups at both 7 and 12 months. Significantly more 19-

month-old children in the recall group (26%) had immunization activity compared to their counterparts who did not receive a recall notification (19%).
Conclusions
Although recall notifications can positively affect immunization activity, the effect may vary by targeted age group. Many 7- and 12-month-olds had immunization activity following reminder/recall; however, levels of activity were similar irrespective of notification, suggesting that these groups were likely to receive medical care or immunization services without prompting.

American Journal of Public Health
Volume 104, Issue 7 (July 2014)
http://ajph.aphapublications.org/toc/ajph/current
[No relevant content]

American Journal of Tropical Medicine and Hygiene
June 2014; 90 (6)
http://www.ajtmh.org/content/current
[Reviewed earlier]

Annals of Internal Medicine
17 June 2014, Vol. 160. No. 12
http://annals.org/issue.aspx
[No relevant content]

BMC Health Services Research
(Accessed 21 June 2014)
http://www.biomedcentral.com/bmchealthservres/content
[No new relevant content]

BMC Infectious Diseases
Accessed 21 June 2014
http://www.biomedcentral.com/bmcinfectdis/content
Research article
Cost effectiveness of a pentavalent rotavirus vaccine in Oman
Salah Thabit Al Awaidy, Berhanu G Gebremeskel, Idris Al Obeidani, Said Al Baqlani, Wisam Haddadin and Megan A O'Brien
BMC Infectious Diseases 2014, 14:334 doi:10.1186/1471-2334-14-334
Published: 17 June 2014
Abstract (provisional)
Background
Rotavirus gastroenteritis (RGE) is the leading cause of diarrhea in young children in Oman, incurring substantial healthcare and economic burden. We propose to formally assess the potential cost effectiveness of implementing universal vaccination with a pentavalent rotavirus

vaccine (RV5) on reducing the health care burden and costs associated with rotavirus gastroenteritis (RGE) in Oman
Methods
A Markov model was used to compare two birth cohorts, including children who were administered the RV5 vaccination versus those who were not, in a hypothetical group of 65,500 children followed for their first 5 years of life in Oman. The efficacy of the vaccine in reducing RGE-related hospitalizations, emergency department (ED) and office visits, and days of parental work loss for children receiving the vaccine was based on the results of the Rotavirus Efficacy and Safety Trial (REST). The outcome of interest was cost per quality-adjusted life year (QALY) gained from health care system and societal perspectives.
Results
A universal RV5 vaccination program is projected to reduce, hospitalizations, ED visits, outpatient visits and parental work days lost due to rotavirus infections by 89%, 80%, 67% and 74%, respectively. In the absence of RV5 vaccination, RGE-related societal costs are projected to be 2,023,038 Omani Rial (OMR) (5,259,899 United States dollars [USD]), including 1,338,977 OMR (3,481,340 USD) in direct medical costs. However, with the introduction of RV5, direct medical costs are projected to be 216,646 OMR (563,280 USD). Costs per QALY saved would be 1,140 OMR (2,964 USD) from the health care payer perspective. An RV5 vaccination program would be considered cost saving, from the societal perspective.
Conclusions
Universal RV5 vaccination in Oman is likely to significantly reduce the health care burden and costs associated with rotavirus gastroenteritis and may be cost-effective from the payer perspective and cost saving from the societal perspective.

BMC Medical Ethics
(Accessed 21 June 2014)
http://www.biomedcentral.com/bmcmedethics/content
[No new relevant content]

BMC Public Health
(Accessed 21 June 2014)
http://www.biomedcentral.com/bmcpublichealth/content
Research article
What interventions are effective on reducing inequalities in maternal and child health in low- and middle-income settings? A systematic review
Beibei Yuan, Mats Malqvist, Nadja Trygg, Xu Qian, Nawi Ng and Sarah Thomsen
Author Affiliations
BMC Public Health 2014, 14:634 doi:10.1186/1471-2458-14-634
Published: 21 June 2014
Abstract (provisional)
Background
The deadline for achieving Millennium Development Goals 4 and 5 is approaching, but inequalities between disadvantaged and other populations is a significant barrier for progress towards achieving these goals. This systematic review aims to collect evidence about the differential effects of interventions on different sociodemographic groups in order to identify interventions that were effective in reducing maternal or child health inequalities.

Methods
We searched the PubMed, EMBASE and other relevant databases. The reference lists of included reviews were also screened to find more eligible studies. We included experimental or observational studies that assessed the effects of interventions on maternal and child health, but only studies that report quantitative inequality outcomes were finally included for analysis.
Results
22 articles about the effectiveness of interventions on equity in maternal and child health were finally included. These studies covered five kinds of interventions: immunization campaigns, nutrition supplement programs, health care provision improvement interventions, demand side interventions, and mixed interventions. The outcome indicators covered all MDG 4 and three MDG 5 outcomes. None of the included studies looked at equity in maternal mortality, adolescent birth rate and unmet need for family planning. The included studies reported inequalities based on gender, income, education level or comprehensive socioeconomic status. Stronger or moderate evidence showed that all kinds of the included interventions may be more effective in improving maternal or child health for those from disadvantaged groups.
Conclusion
Studies about the effectiveness of interventions on equity in maternal or child health are limited. The limited evidence showed that the interventions that were effective in reducing inequity included the improvement of health care delivery by outreach methods, using human resources in local areas or provided at the community level nearest to residents and the provision of financial or knowledge support to demand side.

Research article

A meta-analysis of risk factors for depression in adults and children after natural disasters

Bihan Tang, Xu Liu, Yuan Liu, Chen Xue and Lulu Zhang
Author Affiliations
BMC Public Health 2014, 14:623 doi:10.1186/1471-2458-14-623
Published: 19 June 2014
Abstract (provisional)
Background
A number of studies have shown a range of negative psychological symptoms (e.g. depression) after exposure to natural disasters. The aim of this study was to determine risk factors for depression in both children and adults who have survived natural disasters.
Methods
Four electronic databases (PubMed, Embase, Web of Science, and PsychInfo) were used to search for observational studies (case-control, cross-sectional, and cohort studies) about depression following natural disasters. The literature search, study selection, and data extraction were conducted independently by two authors. Thirty-one articles were included in the study, of which twenty included adult participants and eleven included child participants. Summary estimates were obtained using random-effects models. Subgroup analysis, sensitivity analysis, and publication bias tests were performed on the data.
Results
The prevalence of depression after natural disasters ranged from 5.8% to 54.0% in adults and from 7.5% to 44.8% in children. We found a number of risk factors for depression after exposure to natural disasters. For adults, the significant predictors were being female; not married; holding religious beliefs; having poor education; prior trauma; experiencing fear, injury, or bereavement during the disaster; or losing employment or property ,suffering house damage as a result of the disaster. For children, the significant predictors were prior trauma;

being trapped during the disaster; experiencing injury, fear, or bereavement during the disaster; witnessing injury/death during the disaster; or having poor social support.
Conclusions
The current analysis provides evidence of risk factors for depression in survivors of natural disasters. Further research is necessary to design interventions to improve the mental health of survivors of natural disasters.

British Medical Bulletin
Volume 110 Issue 1 June 2014
http://bmb.oxfordjournals.org/content/current
[Reviewed earlier]

British Medical Journal
21 June 2014 (Vol 348, Issue 7963)
http://www.bmj.com/content/348/7963
[No relevant content]

Bulletin of the World Health Organization
Volume 92, Number 6, June 2014, 385-464
http://www.who.int/bulletin/volumes/92/6/en/
Special theme: BRICS and global health
[Reviewed earlier]

Clinical Infectious Diseases (CID)
Volume 59 Issue 1 July 1, 2014
http://cid.oxfordjournals.org/content/current
Crossing Borders: One World, Global Health
Clive M. Brown and Martin S. Cetron, Section Editors
Rotavirus Enteritis in Dadaab Refugee Camps: Implications for Immunization Programs in Kenya and Resettlement Countries
Maurice Ope, Steve B. Ochieng, Collins Tabu, Nina Marano.
Dadaab refugee camp, established in Kenya in 1991, is host to >500 000 refugees, most of whom are Somali in origin [1]. Annually, the United States resettles approximately 11 000 refugees from Africa, 4000 of them from Kenya. Although substantial progress has been made to provide safe water and improve sanitation in Dadaab, diarrheal disease remains among the leading causes of morbidity and mortality. Several disease outbreaks, including hepatitis E virus [2], cholera [3], and wild poliovirus [4], have been attributed to poor sanitation in the camps…
Editorial comment (C. B.) …Along with the provision of safe water and ensuring proper sanitation and hygiene, important strategies for the control of diarrheal diseases (depending on age) include breastfeeding, using oral rehydration solution, and, if diarrhea is moderate to severe, intravenous fluids, zinc supplementation, and immunization with rotavirus vaccine. Overall, rotavirus vaccine has been shown to be 30% effective against all-cause severe gastroenteritis, and 51%–93% protective against rotavirus gastroenteritis [14–16]. In addition to recommending rotavirus vaccine inclusion in national immunization programs, for countries

where diarrheal deaths account for ≥10% of mortality among children aged <5 years, WHO strongly recommends introduction of the vaccine. The prevalence in this refugee camp was twice that value; thus, evaluating rotavirus vaccine as a childhood vaccine in refugee camps will provide important information for its efficacy in this setting and potentially support attaining MDG4 goals.

Clinical Therapeutics
Volume 36, Issue 6, p817-992 June 2014
http://www.clinicaltherapeutics.com/current
[No relevant content]

Cost Effectiveness and Resource Allocation
(Accessed 21 June 2014)
http://www.resource-allocation.com/
Research
Incremental cost of increasing access to maternal health care services: perspectives from a demand and supply side intervention in Eastern Uganda
Chrispus Mayora, Elizabeth Ekirapa-Kiracho, David Bishai, David H Peters, Olico Okui and Sebastian Olikira Baine
Author Affiliations
Cost Effectiveness and Resource Allocation 2014, 12:14 doi:10.1186/1478-7547-12-14
Published: 19 June 2014
Abstract (provisional)
Introduction
High maternal and infant mortality continue to be major challenges to the attainment of the Millennium Development Goals for many low and middle-income countries. There is now evidence that voucher initiatives can increase access to maternal health services. However, a dearth of knowledge exists on the cost implications of voucher schemes. This paper estimates the incremental costs of a demand and supply side intervention aimed at increasing access to maternal health care services.
Methods
This costing study was part of a quasi-experimental voucher study conducted in two districts in Eastern Uganda to explore the impact of demand and supply - side incentives on increasing access to maternal health services. The provider's perspective was used and the ingredients approach to costing was employed. Costs were based on market prices as recorded in program records. Total, unit, and incremental costs were calculated.
Results
The estimated total financial cost of the intervention for the one year of implementation was US$525,472 (US$1 = 2200UgShs). The major cost drivers included costs for transport vouchers (35.3%), health system strengthening (29.2%) and vouchers for maternal health services (18.2%). The average cost of transport per woman to and from the health facility was US$4.6. The total incremental costs incurred on deliveries (excluding caesarean section) was US$317,157 and US$107,890 for post natal care (PNC). The incremental costs per additional delivery and PNC attendance were US$23.9 and US$7.6 respectively.
Conclusion

Subsidizing maternal health care costs through demand and supply - side initiatives may not require significant amounts of resources contrary to what would be expected. With Uganda's Gross Domestic Product (GDP) per capita of US$551 (2012). Incremental cost per additional delivery represents about 5% of Uganda's GDP per capita to save a mother and probably her new born. For many low income countries, this may not be affordable, yet reliance on donor funding is often not sustainable. Alternative ways of raising additional resources for health must be explored. These include; encouraging private investments in critical sectors such as rural transport, health service provision; mobilizing households to save financial resources for preparedness, and financial targeting for the most vulnerable.

Current Opinion in Infectious Diseases
June 2014 - Volume 27 - Issue 3 pp: v-v 211-302
http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx
[Reviewed earlier]

Developing World Bioethics
April 2014 Volume 14, Issue 1 Pages ii–ii, 1–57
http://onlinelibrary.wiley.com/doi/10.1111/dewb.2014.14.issue-1/issuetoc
[Reviewed earlier]

Development in Practice
Volume 24, Issue 3, 2014
http://www.tandfonline.com/toc/cdip20/current
[No relevant content]

Emerging Infectious Diseases
Volume 20, Number 7—July 2014
http://www.cdc.gov/ncidod/EID/index.htm
[No relevant content

The European Journal of Public Health
Volume 24 Issue 3 June 2014
http://eurpub.oxfordjournals.org/content/current
[Reviewed earlier]

Eurosurveillance
Volume 19, Issue 24, 19 June 2014
http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678
Miscellaneous
Note from the editors: Communication challenges in times of an emerging public health situation
Eurosurveillance editorial team1

European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden

In this issue, Crowford et al. present a perspective in which they turn an experience from their life as scientists during an evolving public health situation into an interesting case study that poses a number of questions well worth discussing [1]. Their description of difficulties in sharing unexpected scientific findings in an emerging situation illustrates the potential for tensions, due to different roles, between three important actors for public health action – scientists, scientific/medical journal editors and policy-makers – whose common denominator is individual/public health.

Facilitating rapid communication to allow public health action has always been core to the mission this journal [2], and we believe that our successful example during the 2009 influenza A(H1N1) pdm09 pandemic has been followed and we are aware that a number of journals now provide possibilities for expedited/fast-track processing of papers. Fast-tracking of peer-reviewed information poses several challenges: scrutinising evidence and disseminating it under time-pressure puts a strain on scientists, editors and public health decision-makers alike. In cases where findings are unexpected and new, and may or may not be plausible for some, such as exemplified in the paper in this issue, these challenges will even be aggravated. In the case study presented, this led to a delay in coordinated communication and publishing in a peer-reviewed journal even though the authors had shared their correct findings early with international organisations and had submitted respective articles to scientific journals.

Another very different example of possible issues around timely communication occurred during the outbreak of severe haemolytic uraemic syndrome caused by Shiga-toxin-producing Escherichia coli O104 in Germany in 2011 [3,4]. Non-validated findings pointing (wrongly) towards cucumbers imported from a specific European country were communicated early by a politician via the media [5] and had considerable economic impact in the country concerned and resulted in political debate about responsibilities and compensation [6,7]. This example shows the dilemma that politicians may face in an evolving situation where expectations to find the source of an outbreak quickly and take measures to stop it are high and they feel pressed to communicate rapidly.

A further example that shows how the different roles of the three parties mentioned above can lead to differing views are the discussions around the publication of the gain-of-function experiments for the influenza A(H5N1) virus led by R Fouchier and Y Kawasoka, in 2012 [8-9]. When the papers were finally published, this was after an intensive debate and resulted in a considerable delay from the initial dates of submission [10-13]. Notwithstanding this, the intense discussions of these papers were valuable for considering the ways in which research is scrutinised and how public health views should also be taken into account in gain-of-function studies even if research should have its freedom as long as the safety (both the workers' and of the general public) are ensured. The list with examples for scientific findings with an impact on individual/public health that lead to communication challenges through associated ethical considerations influenced by diverse perspectives and backgrounds of the actors, is certainly longer and it also played a role in information about the narcolepsy cases that were associated with vaccination with the pandemic vaccine against pandemic influenza A(H1N1) pdm09, Pandemrix, after signals had been detected in Finland and Sweden [14].

The examples above and the paper by Crowcroft et al. show that debate and close cooperation is necessary to strike a balance 'between the proprietary rights of scientists, the needs of public health and the interests of the public' and an important part in this is of course for public health institutes and international organisations such as the European Centre for Disease Prevention and Control and the World Health Organization, to act as an intermediary between researchers and policy makers by assessing risks and the available evidence to

facilitate rapid public health action and with this in mind we agree with the authors that 'When public health is at stake, information must be shared in a structured and transparent manner that communicates the level of uncertainty and meets the needs of all involved.'

Perspectives

The ethics of sharing preliminary research findings during public health emergencies: a case study from the 2009 influenza pandemic

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University of Toronto, Toronto, Ontario, Canada

During the 2009 A(H1N1) influenza pandemic, a suite of studies conducted in Canada showed an unexpected finding, that patients with medically attended laboratory-confirmed pandemic influenza were more likely to have received seasonal influenza vaccination than test-negative control patients. Different bodies, including scientific journals and government scientific advisory committees, reviewed the evidence simultaneously to determine its scientific validity and implications. Decision-making was complicated when the findings made their way into the media. The normal trajectory of non-urgent research includes peer-review publication after which decision-makers can process the information taking into account other evidence and logistic considerations. In the situation that arose, however, the congruence of an unexpected finding and the simultaneous review of the evidence both within and outside the traditional peer-review sphere raised several interesting issues about how to deal with emerging evidence during a public health emergency. These events are used in this article to aid discussion of the complex interrelationship between researchers, public health decision-makers and scientific journals, the trade-offs between sharing information early and maintaining the peer-review quality assurance process, and to emphasise the need for critical reflection on the practical and ethical norms that govern the way in which research is evaluated, published and communicated in public health emergencies.

Global Health: Science and Practice (GHSP)
May 2014 | Volume 2 | Issue 2
http://www.ghspjournal.org/content/current
[No relevant content]

Globalization and Health
[Accessed 21 June 2014]
http://www.globalizationandhealth.com/
[No new relevant content]

Global Public Health
Volume 9, Issue 5, 2014
http://www.tandfonline.com/toc/rgph20/.Uq0DgeKy-F9#.U4onnCjDU1w
[Reviewed earlier]

Health Affairs
June 2014; Volume 33, Issue 6

http://content.healthaffairs.org/content/current
Theme: Economics Of Health Care: Costs, Savings & Value
[Reviewed earlier]

Health and Human Rights
Volume 16, Issue 1
http://www.hhrjournal.org/
Climate Justice and the Right to Health – A Special Issue
[Reviewed earlier]

Health Economics, Policy and Law
Volume 9 - Issue 03 - July 2014
http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue
[Reviewed earlier]

Health Policy and Planning
Volume 29 Issue 3 May 2014
http://heapol.oxfordjournals.org/content/current
[Reviewed earlier]

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)
June 2014 Volume 10, Issue 6
http://www.landesbioscience.com/journals/vaccines/toc/volume/10/issue/6/
[Reviewed earlier]

Infectious Agents and Cancer
[Accessed 21 June 2014]
http://www.infectagentscancer.com/content
[No new relevant content]

Infectious Diseases of Poverty
[Accessed 21 June 2014]
http://www.idpjournal.com/content
[No new relevant content]

International Journal of Epidemiology
Volume 43 Issue 3 June 2014
http://ije.oxfordjournals.org/content/current
[Reviewed earlier]

International Journal of Infectious Diseases
Vol 24 Complete | July 2014 | Pages 1-54
http://www.ijidonline.com/current

Middle East Respiratory Syndrome Corona virus, MERS-CoV. Conclusions from the 2nd Scientific Advisory Board Meeting of the WHO Collaborating Center for Mass Gathering Medicine, Riyadh

Ziad A. Memish, Abdullah Assiri, Rafaat Alhakeem, Saber Yezli, Malak Almasri, Alimuddin Zumla Jaffar A. Al-Tawfiq, Christian Drosten, Ali Albarrak, Eskild Petersen
published online 12 May 2014.

The 2nd Scientific Advisory Board Meeting of the Global Center for Mass Gathering Medicine, Ministry of Health, Riyadh, Kingdom of Saudi Arabia, met April 28 – 29 in Riyadh to discuss risk of infectious diseases and research and surveillance during Hajj. Due to the on-going outbreak of MERS-CoV and especially the recent increase in case detection in Jeddah, (138 MERS cases were reported from Jeddah between 11 to 26 April 2014), the agenda for the second day was focused on MERS-CoV, both in relation to the risk it presents for the forthcoming Umrah during Ramadan and the Hajj, but also in the Kingdom of Saudi Arabia and the Middle East in general. The Ministry of Health used the opportunity to ask the Scientific Advisory Board to review the MERS-CoV situation globally with specific attention to MERS in the country and review case definition, infection control guidelines and risk assessment to nationals, residents, health care workers, family contacts, camel owners, and travelers to KSA, and the future control.

JAMA
June 18, 2014, Vol 311, No. 23
http://jama.jamanetwork.com/issue.aspx
Viewpoint | June 18, 2014

Ethics and Regulatory Complexities for Pragmatic Clinical Trials

Jeremy Sugarman, MD, MPH, MA1,2; Robert M. Califf, MD3,4
Author Affiliations
JAMA. 2014;311(23):2381-2382. doi:10.1001/jama.2014.4164.

Some patients do not receive the best care possible, either because research to support clinical decision making with high-quality evidence is lacking or because evidence-based practices are not routinely implemented.1 Pragmatic clinical trials (PCTs), which include patients in routine clinical practice settings and typically incorporate comparative effectiveness research (CER)—that is, comparing the safety and effectiveness of diagnostic, therapeutic, or delivery system options—can help overcome these challenges. The advent of research methods that use cluster randomization and leverage patient data from electronic health records (EHRs) to increase the sample size of trials at much lower costs is enabling major national initiatives to generate the data needed to improve care. These include the Health Care Systems Research Collaboratory2 and the Patient-Centered Outcomes Research Network (PCORnet).

JAMA Pediatrics
June 2014, Vol 168, No. 6
http://archpedi.jamanetwork.com/issue.aspx
[No relevant content]

Journal of Community Health
Volume 39, Issue 3, June 2014
http://link.springer.com/journal/10900/39/3/page/1
[Reviewed earlier]

Journal of Global Ethics
Volume 10, Issue 1, 2014
http://www.tandfonline.com/toc/rjge20/current#.U2V-Elf4L0l
Tenth Anniversary Forum: The Future of Global Ethics
[Reviewed earlier]

Journal of Health Care for the Poor and Underserved (JHCPU)
Volume 25, Number 2, May 2014
http://muse.jhu.edu/journals/journal_of_health_care_for_the_poor_and_underserved/toc/hpu.25.2.html
[Reviewed earlier]

Journal of Health Organization and Management
Volume 28 issue 3 - Latest Issue
http://www.emeraldinsight.com/journals.htm?issn=1477-7266&show=latest
[No relevant content]

Journal of Infectious Diseases
Volume 210 Issue 1 July 1, 2014
http://jid.oxfordjournals.org/content/current
[Reviewed earlier]

Journal of Global Infectious Diseases (JGID)
Volume 6 | Issue 2 Page Nos. 57-92 April-June 2014
http://www.jgid.org/currentissue.asp?sabs=n
[Reviewed earlier]

Journal of Immigrant and Minority Health
Volume 16, Issue 3, June 2014
http://link.springer.com/journal/10903/16/3/page/1
Special Topics in Immigrant Health: The Health of Indigenous Mayan Migrants from Yucatán México
[Reviewed earlier]

Journal of Medical Ethics
June 2014, Volume 40, Issue 6

http://jme.bmj.com/content/current
[No relevant content]

Journal of Medical Microbiology
June 2014; 63 (Pt 6)
http://jmm.sgmjournals.org/content/current
[Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)
Volume 3 Issue 2 June 2014
http://jpids.oxfordjournals.org/content/current
[Reviewed earlier]

Journal of Pediatrics
Vol 164 | No. 6 | June 2014 | Pages 1245-1504
http://www.jpeds.com/current
[Reviewed earlier]

Journal of Public Health Policy
Volume 35, Issue 2 (May 2014)
http://www.palgrave-journals.com/jphp/journal/v35/n2/index.html
[Reviewed earlier]

Journal of the Royal Society – Interface
July 6, 2014; 11 (96)
http://rsif.royalsocietypublishing.org/content/current
[No relevant content]

Journal of Virology
July 2014, volume 88, issue 13
http://jvi.asm.org/content/current
[No relevant content]

The Lancet
Jun 21, 2014 Volume 383 Number 9935 p2099 - 2184
http://www.thelancet.com/journals/lancet/issue/current
Editorial
Vaccine development and developing countries
The Lancet
Participation of patients in medical research requires that a balance is struck—between anticipated benefits and potential harms of the new treatment being assessed, and with a view

to the broader value of evidence accrued for guiding clinical practice and future research. Tensions can arise, however. Research in low-income settings has sometimes been perceived to be of greater potential benefit to those in high-income countries, where a drug may be marketed after licensing. In an extreme case, at the time of an outbreak of influenza A H5N1 virus in 2006—07, researchers in Indonesia were unable to share clinical samples with their counterparts in high-income countries, owing to a perceived lack of reciprocity for the benefits of research. This disappointing, and unusual, event underscores the need for a shared and participatory agenda in health research.

In today's Lancet, Nita Bhandari and colleagues present an excellent example of successful clinical research in a developing country. They report a phase 3 clinical trial of Rotavac, an oral 116E strain rotavirus vaccine, in India. They document an efficacy of about 54% against severe rotavirus gastroenteritis in infants. Drawing on funding and technical support from Indian and international sources, development of this vaccine against an attenuated human—bovine reassortant virus has taken some 30 years to come to fruition.

Although oral rotavirus vaccines—the licensed Rotarix and RotaTeq—have been available for some years, Rotavac has the potential to be a powerful and affordable vaccination option. India has a larger burden of rotavirus deaths than any other country, with most rotavirus admissions occurring in the first year of life. Rotavac can therefore be expected to be of great benefit in reducing childhood mortality from diarrhoea, contingent on future licensing and introduction in India, and subject to ongoing monitoring of adverse events including intussusception. Availability of an additional rotavirus vaccine could also prove to be of benefit in other developing countries.

In an accompanying Viewpoint, Maharaj Bhan and coauthors describe the collaborative international process which led to the development of Rotavac. They discuss the economic landscape for vaccine development that has influenced the vaccine's creation and will continue to affect its provision alongside competing vaccines. In a Comment in this issue, Brian Greenwood discusses the ethics of randomised vaccine trials. The setting in which a vaccine is to be used, for instance a low-income country, is expected to affect the protection achieved and necessitates rigorous evaluation. In what circumstances, however, is it appropriate for people in a trial's control group to be denied a vaccine of expected health benefit in order to establish efficacy in those allocated by chance to an experimental group? Again the question of balance comes into play, which could involve provision of another licensed vaccine to people in the control group. Questions of this nature will continue to exercise researchers and policy makers, especially in resource-poor countries.

Vaccines cross borders readily given their relative ease of administration and durable effects. Not only have vaccines contributed to long-term health gains in high-income countries and the decisive eradication of smallpox, but vaccination campaigns in developing countries have played an important part in reducing neonatal mortality. Yet the ongoing setbacks in the global mission to control poliomyelitis, which have included violent targeted opposition to polio vaccination projects in Pakistan, emphasise the political dimension of health programmes and of vaccination in particular.

There is no shortage of disease targets in need of vaccines. Although development of vaccines against HIV continues to pose serious challenges for both basic and clinical researchers, vaccines against malaria and dengue (both infectious diseases that cause major burdens of morbidity and mortality concentrated in developing countries) are in advanced stages of clinical assessment. In the future, while development of new vaccines will remain costly in terms of time and research effort, the Rotavac story could prove inspiring for a world planning new health aspirations and challenges for the post-MDG era—a combination of

research creativity and entrepreneurial ingenuity shaping future medical treatments brought about by and for the people of developing countries.

Editorial

World Refugee Day: caring for the forcibly displaced

The Lancet

Preview /

Last week, after jihadist groups took over the second-largest city in Iraq, Mosul, an estimated 300 000 people were forced to leave their homes. Increasing numbers of people are bereft of food, water, or medical care as the conflict continues. WHO expects the health situation to deteriorate because of the complications of bringing human resources and logistics to affected areas. The number of refugees is growing worldwide. 6·5 million people were internally displaced in Syria by the end of last year, with 2·5 million refugees having fled to surrounding countries such as Lebanon, Jordan, and Turkey.

Comment

The use of a placebo in vaccine trials

Brian Greenwood

Preview

Injecting an infant, who cannot consent, with a saline solution that can do no good is not an activity that anyone would want to undertake lightly, yet this is what happens frequently in the course of paediatric vaccine trials. When the efficacy and safety of a novel vaccine is being assessed for the first time, societies, ethics committees, and parents accept this course of action on the grounds that although the vaccinated infant cannot derive any benefit from participating in the trial, other infants might do so in the future.

Comment

116E rotavirus vaccine development: a successful alliance

Shabir A Madhi, Umesh D Parashar

Preview

In The Lancet, Nita Bhandari and colleagues' study1 about the efficacy of the new 116E rotavirus vaccine in Indian infants offers an opportunity to address the substantial lag in translation of scientific progress for the benefit of the world's most vulnerable population. Vaccination is considered to be second only to access to potable water in its potential cost-effectiveness as a health-care strategy for improving child health. Most childhood deaths from vaccine-preventable diseases, such as Haemophilus influenzae type b (Hib), Streptococcus pneumoniae, and rotavirus, happen in low-income countries.

Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian infants: a randomised, double-blind, placebo-controlled trial

Nita Bhandari PhD a, Temsunaro Rongsen-Chandola MSc a, Ashish Bavdekar DNB b, Jacob John MD c, Kalpana Antony MBA d, Sunita Taneja PhD a, Nidhi Goyal DPH a, Anand Kawade MD b, Prof Gagandeep Kang PhD c, Sudeep Singh Rathore MBBS a, Sanjay Juvekar PhD b, Prof Jayaprakash Muliyil DrPH c, Alok Arya MPharm a, Hanif Shaikh MPharm b, Vinod Abraham MPH c, Prof Sudhanshu Vrati PhD e, Michael Proschan PhD f, Robert Kohberger PhD g *, Georges Thiry PhD h, Roger Glass PhD f, Prof Harry B Greenberg MD i, George Curlin MD f, Krishna Mohan PhD j, G V J A Harshavardhan BVSc j, Sai Prasad MBA j, T S Rao PhD k, John Boslego MD m, Dr Prof Maharaj Kishan Bhan MD for the India Rotavirus Vaccine Group

Summary

Background

Rotavirus is the most common cause of severe dehydrating gastroenteritis in developing countries. Safe, effective, and affordable rotavirus vaccines are needed in these countries. We

aimed to assess the efficacy and tolerability of a monovalent human-bovine rotavirus vaccine for severe rotavirus gastroenteritis in low-resource urban and rural settings in India.
Methods
We did a randomised double-blind, placebo-controlled, multicentre trial at three sites in Delhi (urban), Pune (rural), and Vellore (urban and rural) between March 11, 2011, and Nov 5, 2012. Infants aged 6—7 weeks were randomly assigned (2:1), via a central interactive voice or web response system with a block size of 12, to receive either three doses of oral human-bovine natural reassortant vaccine (116E) or placebo at ages 6—7 weeks, 10 weeks, and 14 weeks. Infants' families, study investigators, paediatricians in referral hospitals, laboratory staff, and committee members were all masked to treatment allocation. The primary outcome was incidence of severe rotavirus gastroenteritis (≥11 on the Vesikari scale). Efficacy outcomes and adverse events were ascertained through active surveillance. Analysis was by intention to treat and per protocol. The trial is registered with Clinical Trial Registry—India (CTRI/2010/091/000102) and ClinicalTrials.gov (NCT01305109).
Findings
4532 infants were assigned to receive the 116E vaccine and 2267 to receive placebo, of whom 4354 (96%) and 2187 (96%) infants, respectively, were included in the primary per-protocol efficacy analysis. 71 events of severe rotavirus gastroenteritis were reported in 4752 person-years in infants in the vaccine group compared with 76 events in 2360 person-years in those in the placebo group; vaccine efficacy against severe rotavirus gastroenteritis was 53·6% (95% CI 35·0—66·9; p=0·0013) and 56·4% (36·6—70·1; p<0·0001) in the first year of life. The number of infants needed to be immunised to prevent one severe rotavirus gastroenteritis episode was 55 (95% CI 37—97). The incidence of severe rotavirus gastroenteritis per 100 person-years was 1·5 in the vaccine group and 3·2 in the placebo group, with an incidence rate ratio of 0·46 (95% CI 0·33—0·65). Prevalence of immediate, solicited, and serious adverse events was similar in both groups. One case of urticaria in the vaccine group and one each of acute gastroenteritis and suspected sepsis in the placebo group were regarded as related to the study product. We recorded six cases of intussusception in the vaccine group and two in the placebo group, all of which happened after the third dose. 25 (<1%) infants in the vaccine group and 17 (<1%) in the placebo group died; no death was regarded as related to the study product.
Interpretation
Monovalent human-bovine (116E) rotavirus vaccine is effective and well tolerated in Indian infants.
Funding
Department of Biotechnology and the Biotechnology Industry Research Assistance Council, Government of India; Bill & Melinda Gates Foundation to PATH, USA; Research Council of Norway; UK Department for International Development; National Institutes of Health, Bethesda, USA; and Bharat Biotech International, Hyderabad, India.

Viewpoint

Team science and the creation of a novel rotavirus vaccine in India: a new framework for vaccine development

Maharaj K Bhan, Roger I Glass, Krishna M Ella, Nita Bhandari, John Boslego, Harry B Greenberg, Krishna Mohan, George Curlin, T S Rao

Preview

In The Lancet, findings from Nita Bhandari and colleagues' phase 3 clinical trial1 show the safety and efficacy of the 116E rotavirus vaccine against severe rotavirus gastroenteritis in Indian infants. The vaccine has an efficacy similar to that of two licensed oral rotavirus vaccines—RotaTeq (Merck) and Rotarix (GlaxoSmithKline)—when tested in low-income

settings.2,3 However, the timeline of development has been unique and unconventional. The vaccine was not the product of a major multinational manufacturer, but rather, the result of work by team science, based in India.

The Lancet Global Health
Jun 2014 Volume 2 Number 6 e301 - 363
http://www.thelancet.com/journals/langlo/issue/current
[Reviewed earlier]

The Lancet Infectious Diseases
Jun 2014 Volume 14 Number 6 p441 - 532
http://www.thelancet.com/journals/laninf/issue/current
[Reviewed earlier]

Medical Decision Making (MDM)
July 2014; 34 (5)
http://mdm.sagepub.com/content/current
[Reviewed earlier]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
June 2014 Volume 92, Issue 2 Pages 167–405
http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1468-0009/currentissue
[Reviewed earlier]

Nature
Volume 510 Number 7505 pp312-436 19 June 2014
http://www.nature.com/nature/current_issue.html
Nature | Editorial
Present danger
There is much hype about predicting and preventing future pandemics, but not enough is being done about a threat sitting under our noses.
18 June 2014

Nature Immunology
July 2014, Volume 15 No 7 pp589-694
http://www.nature.com/ni/journal/v15/n6/index.html
Commentary
Toward a Human Vaccines Project - pp589 - 592
Wayne C Koff, Ian D Gust & Stanley A Plotkin
doi:10.1038/ni.2871

Technological advances in antigen discovery, genomics and immunological monitoring offer tremendous potential for revolutionizing vaccine development. On 5–6 February 2014, 35 leading vaccine scientists met to consider how best to harness these advances and spur innovation.

Nature Medicine
June 2014, Volume 20 No 6 pp561-688
http://www.nature.com/nm/journal/v20/n6/index.html
[No relevant content]

Nature Reviews Immunology
June 2014 Vol 14 No 6
http://www.nature.com/nri/journal/v14/n6/index.html
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New England Journal of Medicine
June 19, 2014 Vol. 370 No. 25
http://www.nejm.org/toc/nejm/medical-journal
[No relevant content]

OMICS: A Journal of Integrative Biology
June 2014, 18(6)
http://online.liebertpub.com/toc/omi/18/6
[No new relevant content]

The Pediatric Infectious Disease Journal
July 2014 - Volume 33 - Issue 7 pp: 675-788,e162-e182
http://journals.lww.com/pidj/pages/currenttoc.aspx
Changes in Hospitalizations for Pneumonia After Universal Vaccination With Pneumococcal Conjugate Vaccines 7/13 Valent and Haemophilus influenzae Type b Conjugate Vaccine in a Pediatric Referral Hospital in Uruguay
Pírez, María Catalina MD*; Algorta, Gabriela MD*; Chamorro, Flavia MD*; Romero, Claudia MD*; Varela, Adriana MD†; Cedres, Alejandra MD*; Giachetto, Gustavo MD*; Montano, Alicia MD*
Abstract
Background: In 1994, Uruguay included Haemophilus influenzae b (Hib) conjugated vaccine in a 3 + 1 schedule. In March 2008, 7-valent pneumococcal conjugate vaccines (PCV7) was included in a 2 +1 schedule. In 2010, 13-valent PCV replaced PCV7. Catch-up immunization was offered. The aim of this study was to describe the etiology of community-acquired pneumonia (CAP) in children 0–14 years of age hospitalized at the Hospital Pediatrico-Centro Hospitalario Pereira Rossell between 2003 and 2012.
Methods: Annual hospitalization rates (per 10,000 discharges) for CAP and bacterial-confirmed CAP in children 0–14 years of age was described prior PCV7 vaccination (2003–2007), during the year of implementation of PCV7 (2008) and after the introduction of PCV7 (2009–2012).

Data regarding age, strains isolated from pleural fluid and/or blood, vaccination status, pneumococcal and H. influenzae serotypes were obtained from Hospital Pediatrico-Centro Hospitalario Pereira Rossell databases and vaccination records.
Results: Hospitalization rates for CAP and pneumococcal CAP between prevaccine years and the last year after introduction of vaccination with PCV (2012) significantly decreased by 78.1% and 92.4%, respectively. Significant reduction for 13-valent PCV vaccine serotypes and significant increase for nonvaccine serotypes was observed. A decrease in Staphylococcus aureus pneumonia was observed. Hospitalization rates for H. influenzae CAP remain stable before and after pneumococcal vaccination.
Conclusions: Three years after PCV7/13 introduction into the routine vaccination schedule, there was a rapid and significant reduction in rates of CAP and P-CAP. An increase of etiology of CAP by other agents was not observed.

Pediatrics
June 2014, VOLUME 133 / ISSUE 6
http://pediatrics.aappublications.org/current.shtml
[Reviewed earlier]

Pharmaceutics
Volume 6, Issue 2 (June 2014), Pages 195-
http://www.mdpi.com/1999-4923/6/2
[Reviewed earlier]

Pharmacoeconomics
Volume 32, Issue 7, July 2014
http://link.springer.com/journal/40273/32/7/page/1
Cost-Effectiveness Analysis of Interventions for Tuberculosis Control: DALYs Versus QALYs
R. Diel, N. Lampenius
Abstract
The emergence of multi-drug-resistant tuberculosis (MDR-TB) in the European region and the high costs (nearly €536 million) generated by the nearly 72,000 notified TB cases in the EU are the factors driving the need for development and implementation of new tools against TB. In this context, cost-effectiveness analyses applying quality-adjusted life-years (QALYs) or disability-adjusted life-years (DALYs) as outcome measures for economic evaluation of improved approaches to TB control are increasingly important. While the methodology applied to derive the effectiveness data is commonly reported, less information is given regarding the derivation of utility weights in the calculation of QALYs for TB treatment. To date, despite the particular complexities of the disease, TB health effects have not been fully measured and there is no agreement on how disutility of TB disease should be accounted for. Consequently, disutility values in published studies vary considerably, and often appear to lack empirical evidence. As the need for a solid heath-economics rationale for investment in new tools against TB grows, adequate and comprehensive methods for assessing the impairments caused by different types of TB must be developed. Focusing on the assessment of DALYs as a measure of outcome in economic evaluation, we have built an exemplary model calculation applying the

original TB data for Germany as reported to the Robert Koch Institute. Our work demonstrates that the use of standard equations provided in the scientific literature probably results in an underestimation of lost DALYs compared with probabilistic techniques. Providing distributions around epidemiological averages, coupled with Monte Carlo simulation to address uncertainty, may result in more realistic values. In line with a previous recommendation by the World Health Organization, it appears worthwhile to consider this more intricate approach to providing healthcare resource allocation decisions, particularly for TB.

PLoS One
[Accessed 21 June 2014]
http://www.plosone.org/
Research Article
Improving Ethical and Participatory Practice for Marginalized Populations in Biomedical HIV Prevention Trials: Lessons from Thailand
Dan Allman mail, Melissa Hope Ditmore, Karyn Kaplan
Published: June 20, 2014
DOI: 10.1371/journal.pone.0100058
Abstract
Background
This paper presents findings from a qualitative investigation of ethical and participatory issues related to the conduct of biomedical HIV prevention trials among marginalized populations in Thailand. This research was deemed important to conduct, as several large-scale biomedical HIV prevention trials among marginalized populations had closed prematurely in other countries, and a better understanding of how to prevent similar trial closures from occurring in the future was desired.
Methods
In-depth key informant interviews were held in Bangkok and Chiang Mai, Thailand. Interviews were audio recorded, transcribed, translated and thematically analyzed. The Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials (GPP) guided this work.
Results
Fourteen interviews were conducted: 10 with policymakers, academic and community-based researchers and trial staff and four with representatives of non-governmental organizations (NGOs). Suggested ways to improve ethical and participatory practice centered on standards of HIV prevention, informed consent, communication and human rights. In particular, the need to overcome language and literacy differences was identified. Key informants felt communication was the basis of ethical understanding and trust within biomedical HIV prevention trial contexts, and thus fundamental to trial participants' ability to exercise free will.
Discussion
Biomedical HIV prevention trials present opportunities for inclusive and productive ethical and participatory practice. Key informants suggested that efforts to improve practice could result in better relationships between research stakeholders and research investigative teams and by extension, better, more ethical participatory trials. This research took place in Thailand and its findings apply primarily to Thailand. However, given the universality of many ethical considerations, the results of this study can inform the improvement of ethical and participatory practice in other parts of the world where biomedical HIV prevention trials occur, and where clinical trials in marginalized populations continue.
Research Article

Use of the Carolina HPV Immunization Attitudes and Beliefs Scale (CHIAS) in Young Adult Women

Amanda F. Dempsey mail, Andrea Fuhrel-Forbis, Sara Konrath
Published: June 19, 2014
DOI: 10.1371/journal.pone.0100193
Abstract
Background
Validated measures that can accurate describe young adults' HPV vaccination attitudes and how these relate to vaccination intention and receipt are needed for developing interventions to improve low HPV vaccination levels. The Carolina HPV Immunization Attitudes Scale (CHIAS) is a validated measure of these outcomes that was originally designed for parents.
Objective
To assess the performance of the CHIAS among young adult women using an exploratory factor analysis.
Methods
A convenience sample of 139 young adult women (age 18–26 years) were given the CHIAS measure at baseline. Factor analysis was used to determine attitudinal factor groupings and the association of these factors with HPV vaccination intention. A 6-month follow up assessment examined the stability of the CHIAS over time and the association of baseline vaccine factors with vaccine receipt.
Results
Five factors loaded on to the CHIAS in young adults - "Barriers," "Harms," "Effectiveness," "Risk Denial" and "Uncertainty," - which was similar to the factor loadings of CHIAS for parents. "Harms" was the factor most consistently associated with vaccination intention at all time points assessed. Only 5 women had received or made an appointment to receive the vaccine at the 6-month follow-up.
Conclusions
In terms of categorizing HPV vaccination attitudes, the CHIAS appears to have similar performance among young adults as in parents. However, additional studies are needed to assess the utility of the CHIAS for predicting HPV vaccine receipt among the young adult population.

PLoS Medicine
(Accessed 21 June 2014)
http://www.plosmedicine.org/
Policy Forum

Pediatric Oncology as the Next Global Child Health Priority: The Need for National Childhood Cancer Strategies in Low- and Middle-Income Countries

Sumit Gupta mail, Roberto Rivera-Luna, Raul C. Ribeiro, Scott C. Howard
Published: June 17, 2014
DOI: 10.1371/journal.pmed.1001656
Summary Points
:: As is already the case in high-income countries, cancer represents the leading cause of non-accidental death among children in a growing number of middle-income countries
:: Meaningful declines in global childhood cancer mortality will require moving beyond the current situation through the establishment of national childhood cancer strategies

:: Key components of such strategies include financial coverage, accreditation of childhood cancer centers, mandatory childhood cancer reporting and registration, development of national standards of care, and the creation of national childhood cancer governing bodies
:: Challenges to implementing such strategies include a paucity of implementation research, formal policy evaluation, and costing data
:: The ideal structure of such strategies in low-income countries is currently unknown, given severe resource constraints, deficits in infrastructure, and competing health needs

PLoS Neglected Tropical Diseases
May 2014
http://www.plosntds.org/article/browseIssue.action
[No new relevant content]

PNAS - Proceedings of the National Academy of Sciences of the United States of America
(Accessed 21 June 2014)
http://www.pnas.org/content/early/
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Pneumonia
Vol 5 (2014)
https://pneumonia.org.au/index.php/pneumonia/issue/current
Special Issue "Pneumonia Diagnosis"
[No relevant content]

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Volume 7 Issue 1 April 2014
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Qualitative Health Research
June 2014; 24 (6)
http://qhr.sagepub.com/content/current
[Reviewed earlier; No relevant content]

Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH)
April 2014 Vol. 35, No. 4
http://www.paho.org/journal/index.php?option=com_content&view=article&id=143&Itemid=236&lang=en
[Reviewed earlier]

Risk Analysis
May 2014 Volume 34, Issue 5 Pages 789–980
http://onlinelibrary.wiley.com/doi/10.1111/risa.2014.34.issue-5/issuetoc
[Reviewed earlier; No relevant content]

Science
20 June 2014 vol 344, issue 6190, pages 1317-1424
http://www.sciencemag.org/current.dtl
Policy Forum
Research Capacity
Enabling the genomic revolution in Africa
The H3Africa Consortium
Corresponding author. Charles Rotimi, Center for Research on Genomics and Global Health, National Human Genome Research Institute, NIH, Bethesda, MD 20892–5635, USA
Overview
Our understanding of genome biology, genomics, and disease, and even human history, has advanced tremendously with the completion of the Human Genome Project. Technological advances coupled with significant cost reductions in genomic research have yielded novel insights into disease etiology, diagnosis, and therapy for some of the world's most intractable and devastating diseases—including malaria, HIV/AIDS, tuberculosis, cancer, and diabetes. Yet, despite the burden of infectious diseases and, more recently, noncommunicable diseases (NCDs) in Africa, Africans have only participated minimally in genomics research. Of the thousands of genome-wide association studies (GWASs) that have been conducted globally, only seven (for HIV susceptibility, malaria, tuberculosis, and podoconiosis) have been conducted exclusively on African participants; four others (for prostate cancer, obsessive compulsive disorder, and anthropometry) included some African participants (www.genome.gov/gwastudies/). As discussed in 2011 (www.h3africa.org), if the dearth of genomics research involving Africans persists, the potential health and economic benefits emanating from genomic science may elude an entire continent.

Social Science & Medicine
Volume 115, In Progress (August 2014)
http://www.sciencedirect.com/science/journal/02779536/115
[No new relevant content]

Tropical Medicine and Health
Vol. 42(2014) No. 1
https://www.jstage.jst.go.jp/browse/tmh/42/1/_contents
[Reviewed earlier; No relevant content]

Vaccine
Volume 32, Issue 32, Pages 4013-4110 (7 July 2014)
http://www.sciencedirect.com/science/journal/0264410X/32/32

Vaccination of healthcare personnel: Spotlight on groups with underlying conditions

Original Research Article
Pages 4025-4031
Sabine Wicker, Holly Seale, Laura von Gierke, Helena C. Maltezou

Abstract
Healthcare personnel (HCP) are at increased risk of acquiring vaccine-preventable diseases (VPDs). Vaccination protects HCP and their patients from nosocomial transmission of VPDs. HCP who have underlying diseases (e.g., immunocompromised, HIV-infected, or those with chronic diseases) and HCP in particular phases of life (e.g., pregnant, elderly) require special consideration in regards the provision of vaccines. On the one hand, live virus vaccines may be contraindicated (e.g., pregnant HCP, immunocompromised HCP), while on the other hand, vaccines not routinely recommended (e.g., pneumococcal) may be indicated (e.g., elderly or immunocompromised HCP). It is not known how many HCP with underlying conditions require special consideration in the healthcare setting. This is an important issue, because the risk for serious morbidity, complications and mortality for HCP with underlying conditions will only increase. The prevention of nosocomial infections requires comprehensive occupational safety programs. The healthcare system must engage HCP and occupational physicians to ensure sufficient vaccination rates as part of an effective nosocomial infection prevention and HCP safety strategy.

Evidence-to-policy gap on hepatitis A vaccine adoption in 6 countries: Literature vs. policymakers' beliefs

Original Research Article
Pages 4089-4096
Sachiko Ozawa, Lois A. Privor-Dumm, Angeline Nanni, Emily Durden, Brett A. Maiese, Chizoba U. Nwankwo, Kimberly G. Brodovicz, Camilo J. Acosta, Kathleen A. Foley

Abstract
Background
National vaccine adoption decisions may be better understood by linking multiple data sources. When examining countries' decisions to adopt the hepatitis A vaccine, applying multiple research methods can facilitate assessments of gaps between evidence and policy. We conducted a literature review on hepatitis A and stakeholder interviews about decisions to adopt the vaccine in six countries (Chile, India, South Korea, Mexico, Russia, and Taiwan).
Methods
A systematic literature review was conducted across five literature databases. The review identified and abstracted 340 articles, supplemented by internet search. In addition, we interviewed 62 experts and opinion leaders on hepatitis A and/or vaccines. Data from the two sources were analyzed to identify gaps around epidemiologic data, economic data, and barriers/facilitators of hepatitis A vaccine adoption.
Results
Epidemiologic data gaps were found in Chile and Russia, where stakeholders believed data to be more solid than the literature documented. Economic data on hepatitis A was found to be weak across all countries despite stakeholders' agreement on its importance. Barriers and facilitators of vaccine adoption such as political will, prioritization among vaccines, and global or local recommendations were discussed more by stakeholders than the literature. Stakeholders in India and Mexico were not concerned with the lack of data, despite growing recognition in the literature of the epidemiological transition and threat of outbreaks.
Conclusions

Triangulation of results from two methods captured a richer story behind vaccine adoption decisions for hepatitis A. The discrepancy between policymakers' beliefs and existing data suggest a decline in priority of hepatitis A or weak investment in data collection. Filling the confirmed data gaps in seroprevalence or economic data is important to help guide policy decisions. Greater communication of the risk of hepatitis A and the benefits of the vaccine may help countries undergoing the epidemiologic transition.

The benefits of redesigning Benin's vaccine supply chain

Original Research Article
Pages 4097-4103
Shawn T. Brown, Benjamin Schreiber, Brigid E. Cakouros, Angela R. Wateska, Hamadou M. Dicko, Diana L. Connor, Philippe Jaillard, Mercy Mvundura, Bryan A. Norman, Carol Levin, Jayant Rajgopal, Mélanie Avella, Caroline Lebrun, Erin Claypool, Proma Paul, Bruce Y. Lee

Abstract
Introduction
New vaccine introductions have put strains on vaccine supply chains around the world. While increasing storage and transportation may be the most straightforward options, it is also important to consider what financial and operational benefits can be incurred. In 2012, suboptimal vaccine coverage and impending vaccine introductions prompted the Republic of Benin's Ministry of Health (MOH) to explore ways to improve their vaccine supply chain.
Methods
Working alongside the Beninese MOH, we utilized our computational model, HERMES, to explore the impact on cost and vaccine availability of three possible options: (1) consolidating the Commune level to a Health Zone level, (2) removing the Commune level completely, and (3) removing the Commune level and expanding to 12 Department Stores. We also analyzed the impact of adding shipping loops during delivery.
Results
At baseline, new vaccine introductions without any changes to the current system increased the logistics cost per dose ($0.23 to $0.26) and dropped the vaccine availability to 71%. While implementing the Commune level removal scenario had the same capital costs as implementing the Health Zone scenario, the Health Zone scenario had lower operating costs. This increased to an overall cost savings of $504,255 when implementing shipping loops.
Discussion
The best redesign option proved to be the synergistic approach of converting to the Health Zone design and using shipping loops (serving ten Health Posts/loop). While a transition to either redesign or only adding shipping loops was beneficial, implementing a redesign option and shipping loops can yield both lower capital expenditures and operating costs.

Vaccine: Development and Therapy
(Accessed 21 June 2014)
http://www.dovepress.com/vaccine-development-and-therapy-journal
[No new relevant content]

Vaccines — Open Access Journal
(Accessed 21 June 2014)
http://www.mdpi.com/journal/vaccines
Review:

Novel GMO-Based Vaccines against Tuberculosis: State of the Art and Biosafety Considerations
by Amaya Leunda, Aline Baldo, Martine Goossens, Kris Huygen, Philippe Herman and Marta Romano
Vaccines **2014**, *2*(2), 463-499; doi:10.3390/vaccines2020463 - published online 16 June 2014
Abstract: Novel efficient vaccines are needed to control tuberculosis (TB), a major cause of morbidity and mortality worldwide. Several TB vaccine candidates are currently in clinical and preclinical development. They fall into two categories, the one of candidates designed as a replacement of the Bacille Calmette Guérin (BCG) to be administered to infants and the one of sub-unit vaccines designed as booster vaccines. The latter are designed as vaccines that will be administered to individuals already vaccinated with BCG (or in the future with a BCG replacement vaccine). In this review we provide up to date information on novel tuberculosis (TB) vaccines in development focusing on the risk assessment of candidates composed of genetically modified organisms (GMO) which are currently evaluated in clinical trials. Indeed, these vaccines administered to volunteers raise biosafety concerns with respect to human health and the environment that need to be assessed and managed.

Value in Health
Vol 17 | No. 3 | May 2014
http://www.valueinhealthjournal.com/current
[Reviewed earlier]

WHO South-East Asia Journal of Public Health
Volume 3, Issue 1, January-March 2014, 1-122
http://www.searo.who.int/publications/journals/seajph/issues/whoseajphv3n1/en/
Special Issue on Vector-borne diseases
[Reviewed earlier]

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

Nature Reviews Immunology
Published online: 13 June 2014 doi:10.1038/nri3694
Perspectives
From empiricism to rational design: a personal perspective of the evolution of vaccine development
Ennio De Gregorio & Rino Rappuoli
Abstract
Vaccination, which is the most effective medical intervention that has ever been introduced, originated from the observation that individuals who survived a plague or smallpox would not get the disease twice. To mimic the protective effects of natural infection, Jenner — and later Pasteur — inoculated individuals with attenuated or killed disease-causing agents. This empirical approach inspired a century of vaccine development and the effective prophylaxis of many infectious diseases. From the 1980s, several waves of new technologies have enabled the

development of novel vaccines that would not have been possible using the empirical approach. The technological revolution in the field of vaccination is now continuing, and it is delivering novel and safer vaccines. In this Timeline article, we provide our views on the transition from empiricism to rational vaccine design.

Journal of Acquired Immune Deficiency Syndromes
2014, 66 Suppl 2:S209-16
Lessons Learned From HPV Vaccine Delivery in Low-Resource Settings and Opportunities for HIV Prevention, Treatment, and Care Among Adolescents.
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Abstract
BACKGROUND: Human papillomavirus (HPV) vaccines to prevent cervical cancer have become available in recent years and presented a new challenge to health systems, since they prevent a sexually transmitted virus and are most effective if they are delivered to young adolescent girls, a group not widely served by other health programs. Demonstration and pilot HPV vaccination programs undertaken in the past 7-8 years in low-resource settings have produced lessons that may be more broadly applied to other adolescent health interventions, particularly to those that attempt to reduce human immunodeficiency virus (HIV) infection. METHODS: A systematic literature review was undertaken to identify formal and informal evaluations of HPV vaccine use in low- and middle-income countries. Special attention was devoted to the detailed evaluations carried out on large demonstration projects in India, Peru, Uganda, and Vietnam.
RESULTS: These lessons fall into 2 main categories: service delivery operations and community outreach and mobilization. Operational issues included venue and timing of vaccinations, definition of target population, micro-planning and coordination, integration with other services, and training. Community issues included consent, messages and channels, endorsement and support, and timing of mobilization efforts.
DISCUSSION: Careful planning, good coordination across sectors and levels, and sensitive attention to the expressed needs for information and preferences for communication channels among youth, parents, and communities more broadly were among the key lessons that are relevant for HIV interventions, but many of the smaller details were also important.
CONCLUSIONS: Applying or adapting these lessons to adolescent HIV services could accelerate effective program design and enhance success.

American Journal of Public Health
First Look
Sources of Racial/Ethnic Differences in Awareness of HIV Vaccine Trials
Michael P. Arnold, PhD, MPH, MSW, Michele Andrasik, PhD, Stewart Landers, JD, MCP, Shelly Karuna, MD, MPH, Matthew J. Mimiaga, ScD, MPH, Steven Wakefield, Kenneth Mayer, MD, Susan Buchbinder, MD, and Beryl A. Koblin, PhDMP Arnold, M Andrasik, S Landers, S Karuna… - American journal of public …, 2014
(Am J Public Health. Published online ahead of print June 12, 2014: e1–e7. doi:10.2105/AJPH.2014.301893)
Abstract
Objectives. We explored the relative effects of 2 awareness components—exposure and attention—on racial/ethnic differences in HIV vaccine trial awareness among men who have sex with men (MSM).

Methods. Surveys assessing awareness of and attitudes toward HIV vaccine trials were administered to 1723 MSM in 6 US cities. Proxy measures of exposure included use of HIV resources and other health care services, community involvement, income, and residence. Attention proxy measures included research attitudes, HIV susceptibility, and HIV message fatigue. Using logistic regression models, we assessed the extent to which these proxies accounted for racial/ethnic differences in vaccine trial awareness.
Results. White MSM reported significantly ($P < .01$) higher rates of HIV vaccine trial awareness (22%) compared with Latino (17%), Black (13%) and "other" (13%) MSM. Venue-based exposure proxies and research-directed attitudinal attention proxies were significantly associated with awareness, but only accounted for the White-Latino disparity in awareness. No proxies accounted for the White-Black or White-"other" differentials in awareness.
Conclusions. Sources of disparities in awareness of HIV vaccine trials remain to be explained. Future trials seeking to promote diverse participation should explore additional exposure and attention mediators.

Special Focus Newsletters

RotaFlash
June 20, 2014
http://vad.cmail2.com/t/r-e-xkhdild-mhyjuirjk-j/
Lead Story - 8th African Rotavirus Symposium highlights science, policy, and progress
Delegates empowered to advocate for sustained rotavirus vaccine introduction

Media/Policy Watch

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

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

Al Jazeera
http://www.aljazeera.com/Services/Search/?q=vaccine
Accessed 21 June 2014
[No new, unique, relevant content]

The Atlantic
http://www.theatlantic.com/magazine/
Accessed 21 June 2014
[No new, unique, relevant content]

BBC

http://www.bbc.co.uk/
Accessed 21 June 2014
[No new, unique, relevant content]

Brookings
http://www.brookings.edu/
Accessed 21 June 2014
[No new, unique, relevant content]

Council on Foreign Relations
http://www.cfr.org/
Accessed 21 June 2014
[No new, unique, relevant content]

Economist
http://www.economist.com/
Accessed 21 June 2014
[No new, unique, relevant content]

Financial Times
http://www.ft.com
Accessed 21 June 2014
[No new, unique, relevant content]

Forbes
http://www.forbes.com/
Accessed 21 June 2014
[No new, unique, relevant content]

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 21 June 2014
[No new, unique, relevant content]

Foreign Policy
http://www.foreignpolicy.com/
Accessed 21 June 2014
[No new, unique, relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 21 June 2014
[No new, unique, relevant content]

The Huffington Post
http://www.huffingtonpost.com/
Accessed 21 June 2014
[No new, unique, relevant content]

Le Monde
http://www.lemonde.fr/
Accessed 21 June 2014
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 21 June 2014
[No new, unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 21 June 2014
[No new, unique, relevant content]

Reuters
http://www.reuters.com/
Accessed 21 June 2014
Stalled measles campaign shows health challenge in rebel-held Syria
20 June 2014
By Dasha Afanasieva
ISTANBUL (Reuters) - A measles vaccination program in northern Syria has stalled amid disagreement over who should coordinate it, highlighting the challenges of establishing basic healthcare services in opposition-held parts of the country…

Wall Street Journal
http://online.wsj.com/home-page?_wsjregion=na,us&_homepage=/home/us
Accessed 21 June 2014
[No new, unique, relevant content]

Washington Post
http://www.washingtonpost.com/
Accessed 21 June 2014
Doctors Without Borders: Ebola 'out of control'
Associated Press | Africa | June 20,2014
The Ebola outbreak ravaging West Africa is "totally out of control," according to a senior official for Doctors Without Borders, who says the medical group is stretched to the limit in responding.

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