

Vaccines: The Week in Review

2 January 2011

Center for Vaccine Ethics & Policy (CVEP)

<http://centerforvaccineethicsandpolicy.wordpress.com/>

A program of

- Center for Bioethics, University of Pennsylvania

<http://www.bioethics.upenn.edu/>

- The Wistar Institute Vaccine Center

<http://www.wistar.org/vaccinecenter/default.html>

- Children's Hospital of Philadelphia, Vaccine Education Center

<http://www.chop.edu/service/vaccine-education-center/home.html>

This weekly summary targets news and events in global vaccines ethics and policy gathered from key governmental, NGO and industry sources, key journals and other sources. This summary supports ongoing initiatives of the Center for Vaccine Ethics & Policy, and is not intended to be exhaustive in its coverage. Vaccines: The Week in Review is now also posted in pdf form and as a set of blog posts at <http://centerforvaccineethicsandpolicy.wordpress.com/>. This blog allows full-texting searching of some 2,000 content items.

Comments and suggestions should be directed to

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Editor's Note:

Vaccines: The Week in Review resumes with this 2 January 2012 issue following a holiday break. This issues covers activity from 18 December to 1 January.

Report: Outbreak of wild poliovirus type 1 in China: 20 cases reported

20 December 2011

WHO Europe website

As of 14 December 2011, China has reported 20 cases of wild poliovirus since the outbreak began in August 2011. Of the 20 cases, 11 cases are in adults 19-53 years of age and 9 cases are in children under 3-years-old. The latest case had an onset date of 9 October 2011, and all cases are from the Xinjiang Uygur Autonomous Region of western China.

The Ministry of Health of China has responded to the outbreak by conducting supplementary immunization activities (SIAs) on 8-12 September 2011, which targeted children under 15 years of age and reached a total of 4,065,033 children. A second round, also targeting children age 15 and under was carried out on 8-12 October and reached 4,150,575 children. Vaccination rounds targeting individuals age 15-39 have taken place in a number of prefectures since September 13 and more than 4 million people have been immunized.

Most recently, a third immunization round targeting both children under 15 and adults 15-39 took place on 15-22 November. External WHO and UNICEF monitors reported high coverage, as experienced in previous immunization rounds. The next round of polio SIAs is planned for March 2012.

The Regional Commission for the Certification of Poliomyelitis Eradication in the Western Pacific Region (RCC) met on 14-19 December 2011 in Ha Noi, Viet Nam. At this meeting, the RCC commended China for its efforts to investigate and respond to the

polio outbreak, but it concluded that it was too early to determine whether the outbreak is coming under control. In order for the Region to retain its polio-free certification, 12 months must elapse following the most recent polio case or wild poliovirus isolate (i.e. including the high transmission season of 2012), with surveillance indicators meeting all sensitivity criteria.

WHO notes that wild poliovirus transmission could persist during the low transmission season. Therefore it recommends that the Ministry of Health in China should consider implementing a non-selective, universal mOPV1 vaccination policy for all children younger than 15 years of age during measles SIAs planned for December. Updates about the polio situation in China can be viewed at the WHO Western Pacific Region web site (see link at right).

As in the past, WHO/Europe urges all Member States to remain vigilant and ensure enhanced polio surveillance for wild poliovirus importations and to maintain high coverage with polio vaccine. This is of particular importance for countries with intensive travel and trade routes with China. All those traveling to and from countries or areas reporting wild poliovirus should be vaccinated as per WHO's international travel and health recommendations.

<http://www.euro.who.int/en/what-we-do/health-topics/disease-prevention/vaccines-and-immunization/news/news/2011/12/outbreak-of-wild-poliovirus-type-1-in-china-20-cases-reported>

[Editor's Note: We present three key statements involving the continuing debate around publication of recent H5N1 research on transmissible strains and related biosecurity concerns: The NSABB statement, a WHO statement of concern, and a Washington Post editorial]

Press Statement: National Science Advisory Board for Biosecurity (NSABB) Review of H5N1 Research

The U.S. government remains concerned about the threat of influenza, for the risks it poses seasonally, as well as its potential to cause a pandemic. Our domestic and global influenza surveillance efforts have become increasingly capable, along with expanded vaccine manufacturing capacity and assistance to other countries in their efforts to detect and respond to a pandemic. To enhance the detection of and response to influenza outbreaks, the U.S. government supports a broad range of domestic and global preparedness and response efforts that include research on better diagnostics, vaccines, and therapeutics.

Currently, H5N1 avian influenza virus — the strain commonly referred to as "bird flu" — rarely infects humans and does not spread easily from person to person. However, many scientists and public health officials are concerned that the virus could evolve in nature into a form that is transmissible among humans — an event that could potentially make this deadly virus an extremely serious global public health threat. Thus research on factors that can affect the transmissibility of the H5N1 virus is critically important to international efforts to prepare and prevent threats to public health.

While the public health benefits of such research can be important, certain information obtained through such studies has the potential to be misused for harmful purposes. The National Science Advisory Board for Biosecurity (NSABB) — an independent expert

committee that advises the Department of Health and Human Services (HHS) and other Federal departments and agencies on matters of biosecurity — completed a review of two unpublished manuscripts describing NIH-funded research on the transmissibility of H5N1. These manuscripts — which describe laboratory experiments that resulted in viruses with enhanced transmissibility in mammals — concluded that the H5N1 virus has greater potential than previously believed to gain a dangerous capacity to be transmitted among mammals, including perhaps humans, and describe some of the genetic changes that appear to correlate with this potential.

Following its review, the NSABB decided to recommend that HHS ask the authors of the reports and the editors of the journals that were considering publishing the reports to make changes in the manuscripts. Due to the importance of the findings to the public health and research communities, the NSABB recommended that the general conclusions highlighting the novel outcome be published, but that the manuscripts not include the methodological and other details that could enable replication of the experiments by those who would seek to do harm.

The NSABB also recommended that language be added to the manuscripts to explain better the goals and potential public health benefits of the research, and to detail the extensive safety and security measures taken to protect laboratory workers and the public.

HHS agreed with this assessment and provided these non-binding recommendations to the authors and journal editors.

Recognizing the significant potential benefit of the information about the experimental details to the global influenza surveillance and research communities, the U.S. government is working to establish a mechanism to allow secure access to the information to those with a legitimate need in order to achieve important public health goals. The U.S. government is also developing a proposed oversight policy that would augment existing approaches to evaluating research that has the potential to be misused for harmful purposes.

The NSABB supports the overall goals of the National Institutes of Health, in conducting safe, ethical and informative research to enhance health, lengthen life, and reduce the burdens of illness and disability.

<http://www.nih.gov/news/health/dec2011/od-20.htm>

Statement: WHO concerned that new H5N1 influenza research could undermine the 2011 Pandemic Influenza Preparedness Framework

30 December 2011

The World Health Organization (WHO) takes note that studies undertaken by several institutions on whether changes in the H5N1 influenza virus can make it more transmissible between humans have raised concern about the possible risks and misuses associated with this research. WHO is also deeply concerned about the potential negative consequences. However, WHO also notes that studies conducted under appropriate conditions must continue to take place so that critical scientific knowledge needed to reduce the risks posed by the H5N1 virus continues to increase.

H5N1 influenza viruses are a significant health risk to people for several reasons. Although this type of influenza does not infect humans often, when it does, approximately 60% of those infected die. In addition, because these viruses can cause such severe illness in people, scientists are especially concerned that this type of

influenza could one day mutate so it spreads easily between people and causes a very serious influenza pandemic.

Research which can improve the understanding of these viruses and can reduce the public health risk is a scientific and public health imperative. In order to enable those public health gains, countries where these viruses occur should share their influenza viruses for public health purposes while countries and organizations receiving these viruses should share benefits resulting from the virus sharing. Both types of sharing are on equal footing and equally important parts of the collective global actions needed to protect public health.

While it is clear that conducting research to gain such knowledge must continue, it is also clear that certain research, and especially that which can generate more dangerous forms of the virus than those which already exist, has risks. Therefore such research should be done only after all important public health risks and benefits have been identified and reviewed, and it is certain that the necessary protections to minimize the potential for negative consequences are in place.

In May 2011, the new Pandemic Influenza Preparedness (PIP) Framework came into effect. This Framework was adopted by all WHO Member States as a guide to the sharing of influenza viruses with pandemic potential and the resulting benefits. One specific requirement of this Framework, which pertains to influenza viruses of pandemic potential, and is in keeping with best scientific practice, is for laboratories receiving them through WHO's Global Influenza Surveillance and Response System (GISRS) to collaborate with, and appropriately acknowledge, scientists in countries where the virus originated when initiating research.

WHO recognizes that the scientists who led the work of the new studies received their virus samples from the WHO Global Influenza Surveillance Network (GISN), which preceded GISRS, and before negotiations on the new PIP Framework began. However, now that the Framework has been adopted by all WHO Member States, WHO considers it critically important that scientists who undertake research with influenza viruses with pandemic potential samples fully abide by the new requirements.

Since the PIP Framework represents a major step forward and was agreed upon only after several years of difficult negotiations, WHO stresses that this H5N1 research must not undermine this major public health achievement. WHO will work with Member States and other key parties to ensure scientists understand the new requirements that have been agreed to with the Framework.

Editorial: A flu virus risk worth taking

Washington Post

30 Dec 2011

By Anthony S. Fauci, Gary J. Nabel and Francis S. Collins

Anthony Fauci is director of the National Institute of Allergy and Infectious Diseases (NIAID), Gary Nabel works in the virology laboratory at the NIAID and Francis Collins is director of the National Institutes of Health.

A deadly influenza virus has circulated widely in birds in recent years, decimating flocks but rarely spreading to humans. Nonetheless, because of its persistence in bird flocks, this highly pathogenic virus has loomed as a major public health threat. Seasonal influenza kills less than 1 percent of the people it infects. In contrast, human infections with the H5N1 virus, though exceedingly rare, are fatal in most cases. Should this virus

mutate in a way that allows it to be transmitted as efficiently among people as seasonal influenza viruses are, it could take an unprecedented toll on human life.

A number of important scientific and public health questions regarding this virus remain unanswered, including the likelihood of such mutations arising and the mechanisms by which they may occur. Two recent studies co-funded by the National Institutes of Health have shed light on how this potentially grave human health threat could become a reality. Working carefully with influenza viruses they have engineered in isolated laboratories, scientists in Europe and the United States have identified several mechanisms by which the virus might evolve to transmit efficiently in the ferret, the best animal model for human influenza infection. This research has allowed identification of genetic pathways by which such a virus could be better adapted to transmission among people. This laboratory virus does not exist in nature. There is, however, considerable concern that such a virus could evolve naturally. We cannot predict whether it or something similar will arise naturally, nor when or where it might appear.

Despite these uncertainties, much good can come from generating a potentially dangerous virus in the laboratory. We have to consider the unpredictable and explosive nature of influenza epidemics.

While the World Health Organization and the Centers for Disease Control and Prevention (CDC) provide excellent public health surveillance for novel influenza strains, influenza outbreaks still occur suddenly and in unexpected places. The recent H1N1 pandemic exemplifies the problem: In 2009, a new influenza virus emerged. It was shown to have originated from an animal reservoir, and it spread so rapidly that it strained the pharmaceutical industry's capacity to prepare vaccines fast enough to blunt its spread.

Moreover, we do not fully understand the underlying factors that allow influenza viruses to be transmitted efficiently in humans after they emerge from different species. The ferret transmission studies were intended in part to fill these important gaps in knowledge.

Understanding the biology of influenza virus transmission has implications for outbreak prediction, prevention and treatment. In defining the mutations required for mammalian transmission, public health officials are provided with genetic signatures that, like fingerprints, could help scientists more readily identify newly emergent, potentially harmful viruses, track their spread and detect threatening outbreaks. The ability to identify such viruses even a few months faster than by conventional surveillance provides critical time to slow or stop an outbreak. The CDC provides this health security by implementing public health protective measures, preparing vaccines and stockpiling antiviral drugs. Identifying threatening viruses can also facilitate the early stages of manufacturing vaccines that protect against such a virus in advance of an outbreak.

In addition, determining the molecular Achilles' heel of these viruses can allow scientists to identify novel antiviral-drug targets that could be used to prevent infection in those at risk or to better treat those who become infected. Decades of experience tell us that disseminating information gained through biomedical research to legitimate scientists and health officials provides a critical foundation for generating appropriate countermeasures and, ultimately, protecting public health.

The underlying question, of course, is whether the benefits of such research outweigh the risks. The answer is not simple. A highly pathogenic avian influenza virus transmissible in humans could arise in ways not predicted by laboratory studies. And it is

not clear whether the laboratory virus would behave in humans as it does in ferrets. Nonetheless, new data can provide valuable insights that would inform influenza preparedness and help delineate the principles of influenza virus transmission between species.

Along with support for this research comes a responsibility to ensure that the information is used for good. Safeguarding against the potential accidental release or deliberate misuse of laboratory pathogens is imperative. The engineered viruses developed in the ferret experiments are maintained in high-security laboratories. The scientists, journal editors and funding agencies involved are working together to ensure that access to specific information that could be used to create dangerous pathogens will be limited to those with an established and legitimate need to know.

http://www.washingtonpost.com/opinions/a-flu-virus-risk-worth-taking/2011/12/30/gIQAM9sNRP_story.html

GAVI announced new support from the Swedish Ministry of Foreign Affairs which will contribute US\$55.5 million to support its 2012 immunisation programmes. The contribution includes an additional US\$18.5 million from Sweden's initial commitment, which was announced at the GAVI pledging conference on 13 June 2011. Sweden is the first GAVI donor to further increase its contribution following the conference. **GAVI also expressed "its deep appreciation" to the U.S. for an increase in funding** secured in the Fiscal Year 2012 omnibus spending bill passed by the US Congress on 17 December. The omnibus bill recommends that GAVI receive US\$100 million, an increase of US\$10.2 million over the US\$89.8 million appropriated in FY2011. Seth Berkley, CEO of the GAVI Alliance, commented, "Working with our partners, including USAID, we aim to immunise a quarter of a billion children by 2015. We are grateful, that despite significant fiscal constraints, Congress has approved funding that will allow us to continue this important work and build on the measurable results we've achieved over more than a decade."

<http://www.gavialliance.org/library/news/press-releases/2011/sweden-increases-funding-for-immunisation/>

<http://www.gavialliance.org/library/news/statements/2011/gavi-appreciation-for-fy2012-appropriations-passed-by-us-congress/>

Meeting: 130th WHO Executive Board session

Date: 16–23 January 2012

Location: Geneva, Switzerland

Provisional Agenda: http://apps.who.int/gb/ebwha/pdf_files/EB130/B130_1-en.pdf

[Editor's Note: The provisional agenda includes a number of issues relating to global immunization and vaccines supported in part by the documents highlighted just below.

We note with interest the agenda item "Draft global vaccine action plan: update [EB130/21](#) associated with the on-going Decade of Vaccine Collaboration (DoVC) and include initial paragraphs and the closing requested action by the WHO Executive Board.

Further below we note the availability and selected items from the provisional agenda for the World Health Assembly meeting to be held in May 2012, which also includes treatment of the Global Vaccine Action Plan (GVAP).]

[EB130/13](#)

Monitoring of the achievement of the health-related Millennium Development Goals
Progress in the achievement of the health-related Millennium Development Goals and global health goals after 2015

[EB130/16](#)

Implementation of the International Health Regulations (2005)

[EB130/17](#)

Global mass gatherings: implications and opportunities for global health security

[EB130/18](#)

Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: report of the Advisory Group

[EB130/19](#)

Poliomyelitis: intensification of the global eradication initiative

[EB130/21](#)

***Draft global vaccine action plan: update
Report by the Secretariat***

[Initial paragraphs and closing action request; full document (6 pages) available at http://apps.who.int/gb/ebwha/pdf_files/EB130/B130_21-en.pdf]

1. This document summarizes progress in the development of the global vaccine action plan that was initially discussed by the Sixty-fourth World Health Assembly in 2011 as part of the progress report on the implementation of the Global Immunization Vision and Strategy.¹ The final version of the action plan will be presented to the Sixty-fifth World Health Assembly in May 2012.

THE GLOBAL VACCINE ACTION PLAN – AN IMMUNIZATION AGENDA FOR THE DECADE OF VACCINES

2. The Decade of Vaccines (2011–2020) envisages a world in which all individuals and communities enjoy lives that are free from vaccine-preventable diseases. Its purpose is to extend, by 2020 and beyond, the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live.

3. In May 2011, the Sixty-fourth World Health Assembly noted the report on the Global Immunization Vision and Strategy 2006–2015, the first 10-year strategic framework to realize the potential of immunization in addressing morbidity and mortality from vaccine-preventable diseases. It has been a global rallying point, enabled the design of regional strategies, and guided the development of comprehensive, fully costed, multi-year national plans for immunization. The report to the Health Assembly included a description of the start of the collaborative process to develop a global vaccine action plan that builds on the success of the Global Immunization Vision and Strategy. The action plan aims to go further, integrating all aspects of immunization, including research and development, delivery, access to quality vaccines that are affordable, and public and political support. The action plan will also include projections of financial resource availability and requirements, and a clear process to define an accountability framework, arrived at through a comprehensive global, regional, and in-country consultation process...

ACTION BY THE EXECUTIVE BOARD

29. The Executive Board is invited to take note of the report and provide further guidance to support the preparation of the final draft of the global vaccine action plan.
1: Document A64/14.

Provisional Agenda for the Sixty-fifth World Health Assembly (May 2012)
EB130/33: http://apps.who.int/gb/ebwha/pdf_files/EB130/B130_33-en.pdf The agenda includes the following items of special interest regarding immunization and vaccines issues:

13. Technical and health matters

13.9 Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: report on the work of the Advisory Group

13.10 Poliomyelitis: intensification of the global eradication initiative

13.11 Elimination of schistosomiasis

13.12 Draft global vaccine action plan

13.16 Progress reports

Disease eradication, prevention and control

D. Smallpox eradication: destruction of variola virus stocks (resolution WHA60.1)

E. Eradication of dracunculiasis (resolution WHA64.16)

F. Chagas disease: control and elimination (resolution WHA63.20)

G. Viral hepatitis (resolution WHA63.18)

H. Prevention and control of multidrug-resistant tuberculosis and extensively drug resistant tuberculosis (resolution WHA62.15)

I. Cholera: mechanisms for control and prevention (resolution WHA64.15)

J. Control of human African trypanosomiasis (resolution WHA57.2)

K. Global health sector strategy on HIV/AIDS, 2011–2015 (resolution WHA64.14)

L. Prevention and control of sexually transmitted infections: global strategy (resolution WHA59.19)

The Decade of Vaccines (DoV) Collaboration announced new appointments in its structure. Dr. Seth Berkley, GAVI CEO, will be transitioning from his previous role on the Steering Committee to join the Leadership Council – the body responsible for providing guidance and strategic input toward the development of a global vaccine action plan, aiming to extend the full benefits of immunization to all people. Dr. Ciro de Quadros was appointed as Steering Committee Co-Chair. Dr. de Quadros, already active in the Collaboration, will be replacing Dr. Christopher Elias, who will be taking on a new role as a Leadership Council member.

<http://www.dovcollaboration.org/leadership-appointments/>

GSK said it will provide an additional 180 million doses of its Synflorix pneumococcal vaccine to GAVI over the next 12 years to help expand immunisation programmes against pneumococcal disease to 72 developing countries by 2023. The action “builds on the 300 million doses that GSK committed to GAVI in March 2010 through an innovative financing mechanism known as the Advance Market Commitment (AMC). In total, up to 160 million children in developing countries could now be protected with Synflorix against pneumococcal disease by 2023.”

GSK noted that it is providing the additional 180 million doses of Synflorix to GAVI "at a small fraction of developed world prices."

<http://www.gsk.com/media/pressreleases/2011/2011-pressrelease-815404.htm>

The U.S. Food and Drug Administration said it approved Prevnar 13, a pneumococcal 13-valent conjugate vaccine, for people ages 50 years and older to prevent pneumonia and invasive disease caused by the bacterium, *Streptococcus pneumoniae*. Karen Midthun, M.D., director of FDA's Center for Biologics Evaluation and Research, said, "According to recent information for the United States, it is estimated that approximately 300,000 adults 50 years of age and older are hospitalized yearly because of pneumococcal pneumonia. Pneumococcal disease is a substantial cause of illness and death. Today's approval provides an additional vaccine for preventing pneumococcal pneumonia and invasive disease in this age group." FDA noted that the new use for Prevnar 13 was approved under the agency's accelerated approval pathway, which allows for earlier approval of treatments for serious and life-threatening illnesses. The pathway allows for the demonstration of effectiveness of a vaccine using an immune marker that is reasonably likely to predict clinical benefit.
<http://www.prnewswire.com/news-releases/fda-expands-use-of-prevnar-13-vaccine-for-people-ages-50-and-older-136440078.html>

WHO's SAGE announced that it is establishing a new SAGE Working Group "on communication and dealing with vaccine hesitancy" and is soliciting proposals for experts to serve on this working group." The terms of reference and expertise for the group are available here: [Terms of reference and required expertise pdf, 16kb](#) Proposals for nominations should be sent by email to sageexecsec@who.int with Curriculum Vitae and indication of expertise and no later than Tuesday 17 January 2012.
http://www.who.int/immunization/sage/working_group_communication_dec2011/en/ind ex.html

The NIH announced that it established the National Center for Advancing Translational Sciences (NCATS) "in a move to re-engineer the process of translating scientific discoveries into new drugs, diagnostics, and devices" with a budget of US\$575 million. NCATS "will serve as the nation's hub for catalyzing innovations in translational science. Working closely with partners in the regulatory, academic, nonprofit, and private sectors, NCATS will strive to identify and overcome hurdles that slow the development of effective treatments and cures." NIH Director Dr. Francis S. Collins, M.D., Ph.D. commented, "Congressional support for the National Center for Advancing Translational Sciences marks a major milestone in mobilizing the community effort required to revolutionize the science of translation. Patients suffering from debilitating and life threatening diseases do not have the luxury to wait the 13 years it currently takes to translate new scientific discoveries into treatments that could save or improve

the quality of their lives. The entire community must work together to forge a new paradigm, and NCATS aims to catalyze this effort.”

<http://www.nih.gov/news/health/dec2011/od-23.htm>

The MMWR Weekly for December 23, 2011 / Vol. 60 / No. 50 includes:

- [Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males — Advisory Committee on Immunization Practices \(ACIP\), 2011](#)
- [Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\)](#)

Twitter Watch 21 December 2011 – 1 January 2012

Items of interest from a variety of twitter feeds associated with immunization, vaccines and global public health. This capture is highly selective and is by no means intended to be exhaustive.

[UNICEF](#) UNICEF

Video Report: UNICEF in 2011 - The year in review ~~~ uni.cf/yearofthechild ~~~

[@UN](#) [#Flood](#) [#Food](#) [#Water](#) [#Conflict](#) [#Children](#)

[31 Dec](#)

[KaiserFamFound](#) Kaiser Family Found

30 years of [#AIDS](#) – see the milestones in this interactive timeline ow.ly/887w2

[31 Dec](#)

[IHME UW](#) IHME at UW

The STEPS NCD Risk Factors Survey, developed by WHO, is used by countries to measure major risk factors. [#GHDxdata](#) bit.ly/rD2ynK

[30 Dec](#)

[WHO](#) WHO

WHO concerned that new [#H5N1](#) flu research could undermine the 2011 Pandemic Influenza Preparedness Framework. bit.ly/uR47nz

[30 Dec](#)

[UNICEF](#) UNICEF

The Government of Japan has announced a pledge of US\$9.3 million to fund polio eradication efforts in Afghanistan uni.cf/sDQqYh

[29 Dec](#)

[PATHtweets](#) PATH

RT [@PSIHealthyLives](#) PSI CEO Karl Hofmann evaluates the top 10 [#GlobalHealth](#) achievements in 2011: ow.ly/8dcgR [#whyforeignaid](#)

[29 Dec](#)

[USAIDGH](#) USAID Global Health

Eleven Global Health Events in 2011 [#globalhealth](#) tinyurl.com/bw869rr

[29 Dec](#)

[ArthurCaplan](#) Arthur Caplan

Making microbes, keeping secrets on.msnbc.com/t4NtN1

[27 Dec](#)

[AIDSvaccine](#) IAVI

New issue of IAVI Report incl look at [#flu](#) [#vaccine](#) pipeline & recap of recent [#HIV](#) vaccine-related meetings: bit.ly/rpuLeG [#research](#)

[27 Dec](#)

[UNICEF](#) UNICEF

Simultaneous [#measles](#) and [#polio](#) vaccination drives to protect [#children](#) in [#DRCongo](#) ~~~ uni.cf/uqSp84 ~~~ [@UNICEFPolio](#) [@endpolionow](#)

[26 Dec](#)

[GAVISeth](#) Seth Berkley

It has been an incredible year. I bring to GAVI my IAVI tradition of writing an EOY letter. Read my reflections on 2011 ht.ly/88Nmp

[23 Dec](#)

[cdcchep](#) CDC Hepatitis

New ACIP recommendation for [#HepB](#) vaccination for adults w/ diabetes now published in [@CDCMMWR](#) go.usa.gov/NyH [#Hepatitis](#) [#HBV](#)

[22 Dec](#)

[GoHealthyPeople](#) Healthy People 2020

Recommended immunizations are an important part of preparedness and are free under the [#ACA](#): 1.usa.gov/rkUmOl.

[22 Dec](#)

[GAVIAlliance](#) GAVI Alliance

Swedish Ministry of Foreign Affairs announced it will contribute \$55.5M to [#GAVI](#) to support [#immunization](#) programmes- ht.ly/8733Z

[21 Dec](#)

Journal Watch

Vaccines: The Week in Review continues its weekly scanning of key 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

Annals of Internal Medicine

December 20, 2011; 155 (12)

<http://www.annals.org/content/current>

[No relevant content]

British Medical Bulletin

Volume 100 Issue 1 December 2011

<http://bmb.oxfordjournals.org/content/current>

[Reviewed earlier; No relevant content]

British Medical Journal

24 December 2011 (Vol 343, Issue 7837)

<http://www.bmj.com/content/current>

[No relevant content]

Cost Effectiveness and Resource Allocation

(Accessed 1 January 2012)

<http://www.resource-allocation.com/>

[No new relevant content]

Emerging Infectious Diseases

Volume 18, Number 1—January 2012

<http://www.cdc.gov/ncidod/EID/index.htm>

Research

Use of Lean Response to Improve Pandemic Influenza Surge in Public Health Laboratories

J. L. Isaac-Renton et al.

Abstract

A novel influenza A (H1N1) virus detected in April 2009 rapidly spread around the world. North American provincial and state laboratories have well-defined roles and responsibilities, including providing accurate, timely test results for patients and information for regional public health and other decision makers. We used the multidisciplinary response and rapid implementation of process changes based on Lean methods at the provincial public health laboratory in British Columbia, Canada, to improve laboratory surge capacity in the 2009 influenza pandemic. Observed and computer simulating evaluation results from rapid processes changes showed that use of Lean tools successfully expanded surge capacity, which enabled response to the 10-fold increase in testing demands.

Modeling Insights into Haemophilus influenzae Type b Disease, Transmission, and Vaccine Programs

M. L. Jackson et al.

Abstract

In response to the 2007–2009 Haemophilus influenzae type b (Hib) vaccine shortage in the United States, we developed a flexible model of Hib transmission and disease for optimizing Hib vaccine programs in diverse populations and situations. The model classifies population members by age, colonization/disease status, and antibody levels, with movement across categories defined by differential equations. We implemented the model for the United States as a whole, England and Wales, and the Alaska Native population. This model accurately simulated Hib incidence in all 3 populations, including the increased incidence in England/Wales beginning in 1999 and the change in Hib incidence in Alaska Natives after switching Hib vaccines in 1996. The model suggests that a vaccine shortage requiring deferral of the booster dose could last 3 years in the United States before loss of herd immunity would result in increasing rates of invasive Hib disease in children <5 years of age.

Global Health

Winter 2012

http://www.globalhealthmagazine.com/in_this_issue/

- [When Words Fail](#)
- [The Decade of Vaccines Collaboration](#)
- [The Art of Making Vaccines More Affordable](#)
- [Vaccines: A Top Priority for Global Health](#)
- [Vaccination Week in the Americas Goes Global](#)
- [On the Brink of a Watershed Moment for HIV Vaccine R&D](#)

Globalization and Health

[Accessed 1 January 2012]

<http://www.globalizationandhealth.com/>

[No new relevant content]

Health Affairs

December 2011; Volume 30, Issue 12

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

Variety Issue

[No relevant content]

Health and Human Rights

Vol 13, No 2 (2011)

<http://hhrjournal.org/index.php/hhr>

[Reviewed earlier]

Health Economics, Policy and Law

Volume 6 - Issue 04 - 06 September 2011

<http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue>

[Reviewed earlier]

Health Policy and Planning

Volume 27 Issue 1 January 2012

<http://heapol.oxfordjournals.org/content/current>

Commentaries

Anne Mills

Health policy and systems research: defining the terrain; identifying the methods

Health Policy Plan. (2012) 27(1): 1-7 doi:10.1093/heapol/czr006

Abstract

Across low- and middle-income countries on the one hand, and high-income countries on the other, there is confusion in the terminology relating to the study of health services and health systems. This commentary discusses health policy and systems research (HPSR) methods, drawing on the health services research literature and on recent work on HPSR. An earlier version of the text was written to contribute to discussions at a meeting organized by the Alliance for Health Policy and Systems Research, an agency set up in 1998 to promote and support such research in low- and middle-income countries. The paper comments on the field of HPSR methods, suggests priorities and identifies challenges facing the field of HPSR.

Thomas J Bossert

Health systems

Health Policy Plan. (2012) 27(1): 8-10 doi:10.1093/heapol/czr008

There is an avalanche of interest in health systems with countries, donors, international experts and academic institutions all rushing to promote, fund or build capacity to address this wave of interest. As Anne Mills documents in an article in this volume, there is also a growing literature on how to think about health systems, how to use research on health systems to improve their performance, and pleas for greater investment in knowledge about health systems. We are probably riding on the crest of this new wave and it will be important to make use of it to further our knowledge about how to achieve health system effectiveness. With continuing global economic uncertainty, this wave may pass if we do not take advantage of it now.

It is useful to reflect on why there is such interest in this theme now. There are probably many converging causes but the most important, to my mind, is a replay of an old debate between vertical programmes and horizontal, integrated approaches that has experienced swings of interest at least since the Alma Ata Conference in 1978 emphasized the integrated primary health care approach. During the last decade or more, there has been a major focus on vertical disease-specific programmes supported by greatly increased funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria, Global Alliance for Vaccines and Immunisation (GAVI), US President's Emergency Plan for AIDS Relief (PEPFAR), Bill and Melinda Gates Foundation, among other donors. The major claim of these programmes was that by focusing on clear disease-specific objectives they would be more effective in shorter time periods and they could be held more accountable to donors (since the results could be more measurable) than the difficult and diverse efforts to improve the many elements of a health system through the horizontal ...

Human Vaccines

Volume 7, Issue 12 December 2011

<http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/12/>

[Reviewed earlier]

Forthcoming Issues available here:

<http://www.landesbioscience.com/journals/vaccines/forthcoming/>

International Journal of Infectious Diseases

Volume 15, Issue 12, Pages e807-e888 (December 2011)

<http://www.sciencedirect.com/science/journal/12019712>

[Reviewed earlier; No relevant content]

JAMA

<http://jama.ama-assn.org/current.dtl>

December 28, 2011, Vol 306, No. 24, pp 2643-2742

[No relevant content]

December 21, 2011, Vol 306, No. 23, pp 2537-2633

Global Health

Community Protection From Pneumococcus Infection

M. J. Friedrich

JAMA. 2011;306(23):2553.doi:10.1001/jama.2011.1806

Vaccination of young Gambian children against the pneumococcus bacterium reduced the carriage of vaccine-type pneumococci not only in vaccinated children but also in nonvaccinated older children and adults, reports an international team of researchers (Roca A et al. PLoS Med. 2011;8[10]:e1001107).

In a cluster randomized trial involving 21 rural villages in western Gambia, all residents in the intervention villages received the 7-valent pneumococcal conjugate vaccine; in the control villages, only children younger than 30 months received the vaccine. The prevalence of nasopharyngeal carriage of vaccine-type pneumococcal serotypes was reduced in both the intervention and control villages in all age groups, revealing a potential herd effect from vaccination of young children. Vaccinating an entire village did not lead to an increase in non-vaccine-type strains for 2 years after vaccination.

Further long-term studies are planned.

Journal of Infectious Diseases

<http://www.journals.uchicago.edu/toc/jid/current>

Volume 205 Issue 2 January 15, 2012

Editorial Commentaries

Stephen L. Cochi and Robert W. Linkins

The Final Phase of Polio Eradication: New Vaccines and Complex Choices

J Infect Dis. (2012) 205(2): 169-171 doi:10.1093/infdis/jir727

Extract

The Global Polio Eradication Initiative (GPEI) made rapid progress after its launch by the World Health Assembly in 1988, reducing polio cases by more than 99% from an estimated 350 000 in 1988 to 719 cases in 2000. However, further progress toward eradicating polio stalled after 2000 in a handful of tropical endemic countries, and the international spread of the virus from these endemic areas led to recurrent outbreaks in previously polio-free countries. One factor related to the stalled progress was the well-documented lower immunogenicity and effectiveness in tropical developing countries of oral poliovirus vaccine (OPV) [1, 2], so attention focused on developing and licensing monovalent type 1 and type 3 vaccines to improve the effectiveness of vaccination by avoiding cross-interference between the 3 serotypes that occurs following vaccination with the traditional trivalent OPV (tOPV). This issue of the Journal contains the most recent in a series of 3 clinical trials in 2 African (Egypt, South Africa) countries and 1 Asian (India) country, demonstrating the superior type-specific immunogenicity in developing countries of monovalent oral poliovirus vaccines (mOPVs), as compared with tOPV [3–6]. In particular, the 3 trials demonstrate the superior immune responses of monovalent OPV type 1 (mOPV1) and type 3 (mOPV3) compared with tOPV, either following 1 dose of vaccine given to newborn infants (in Egypt and South Africa), or 2 doses given at birth and 1 month of age (in India).

Monovalent or bivalent (types 1 and 3) OPV can overcome some of the limitations of tOPV, including the interference among the 3 Sabin strains. Because the type-2 component of tOPV replicates more efficiently and is considerably more immunogenic than the other components ...

Melinda A. Beck

Influenza and Obesity: Will Vaccines and Antivirals Protect?

J Infect Dis. (2012) 205(2): 172-173 doi:10.1093/infdis/jir740

Extract

There is a worldwide pandemic of obesity. The World Health Organization estimates 500 million adults and almost 43 million children under the age of 5 years to be obese (body mass index >30) [1]. According to the Centers for Disease Control and Prevention, nearly one-third of the adult US population is obese. Obesity has been definitively linked to a wide range of comorbidities, including increased coronary heart disease, type 2 diabetes, hypertension, and dyslipidemia [2]. Beyond the contribution of obesity to these chronic diseases, surprisingly little attention has been given to the effects of obesity on the immune response to infectious diseases.

Several studies have now reported that obesity was associated with a poor outcome following infection with 2009 pandemic influenza (pH1N1) [3–7]. Kwong and colleagues reported that obese individuals, in addition to being at risk from pH1N1, were also at greater risk for hospitalization from seasonal influenza infection [8]. In sum, these reports demonstrate that obesity increases the risks associated with influenza infection.

Beyond these clinical studies on the role of obesity in influenza infection, 2 studies in this issue of the Journal using a mouse model and pH1N1 infections provide new insights into obesity's effect on the immune response to influenza virus infection and the ability of vaccination or antiviral treatment to mitigate the effects of infection.

Vaccination remains our ...

BACTERIA

Jennifer R. Scott, Eugene V. Millar, Marc Lipsitch, Lawrence H. Moulton, Robert Weatherholtz, Mindy J. Perilla, Delois M. Jackson, Bernard Beall, Mariddie J. Craig, Raymond Reid, Mathuram Santosham, and Katherine L. O'Brien
Impact of More Than a Decade of Pneumococcal Conjugate Vaccine Use on Carriage and Invasive Potential in Native American Communities

J Infect Dis. (2012) 205(2): 280-288 doi:10.1093/infdis/jir730

Abstract

Background. We assessed the impact of 12 years of pneumococcal conjugate vaccine (PCV7) use on pneumococcal nasopharyngeal carriage and serotype-specific invasive disease potential among Native Americans.

Methods. Families were enrolled in a carriage study from 2006 to 2008; nasopharyngeal specimens and risk factor information were collected monthly for 7 visits. Pneumococcal carriage prevalence was compared with that before (1998–2000) and during (2001–2002) PCV7 introduction. We compared invasive disease incidence and carriage prevalence before and after PCV7 introduction to estimate changes in serotype-specific invasive potential.

Results. We enrolled 1077 subjects from 302 households. There was an absolute reduction in carriage prevalence of 8.0% (95% confidence interval [CI], 4.5%–11.4%) in children aged <5 years and 3.1% (95% CI, 1.1%–5.1%) in adults. In children aged <5 years, vaccine-serotype carriage prevalence decreased by 22.8% (95% CI, 20.1%–25.3%), and nonvaccine serotype (NVT) increased by 15.9% (95% CI, 12.4%–19.3%). No significant change was detected in serotype-specific invasive potential after PCV7 introduction.

Conclusions. Pneumococcal carriage prevalence decreased in all ages since PCV7 introduction; vaccine-serotype carriage has been nearly eliminated, whereas the prevalence of NVT carriage has increased. The increase in the NVT invasive disease rate seems to be proportional to the increase in colonization prevalence.

Volume 205 Issue 1 January 1, 2012

[No relevant content]

The Lancet

Dec 17, 2011 Volume 378 Number 9809 p2049 – 2138 e22 - 28

<http://www.thelancet.com/journals/lancet/issue/current>

[Reviewed earlier; No relevant content]

The Lancet Infectious Disease

Jan 2012 Volume 12 Number 1 p1 - 88

<http://www.thelancet.com/journals/laninf/issue/current>

Editorial

Investing wisely in HIV/AIDS

The Lancet Infectious Diseases

Preview

Ahead of World AIDS Day on Dec 1, 2011, WHO, UNICEF, and UNAIDS launched the Global HIV/AIDS Response 2011 progress report on Nov 30. The report is the fifth such annual report published since 2006. As John Zarocostas reports in this month's

Newsdesk, the latest edition contains much good news on treatment and prevention, but the gains made by past efforts are jeopardised by the ongoing global financial crisis and dwindling funds.

Estimating the effect of influenza vaccines

Heath Kelly, Marta Valenciano

Preview

In *The Lancet Infectious Diseases*, Michael Osterholm and colleagues report a meta-analysis¹ on the efficacy and effectiveness of influenza vaccines licensed in the USA. Although not confined to country of licensure, similar analyses have been published by the Cochrane collaboration.² However, this new study¹ differs in several ways from the Cochrane analyses.

Comment

Mass gatherings medicine

Ziad A Memish, Gwen Stephens, Adullah Al Rabeeah

Preview

Between the eighth and 12th days of Dhu al-Hajjah, the 12th month of the Islamic calendar, Saudi Arabia welcomed 3 million people to Mecca for the annual Hajj pilgrimage. As Hajj ended in mid-November, the country had many reasons to be grateful. Risk of injury and death during the pilgrimage has fallen since 2007, with redesigned venues and modern crowd-control strategies. Medical treatment for injuries, infections, and various chronic diseases will have been provided to thousands. Despite intense crowding and the diversity of ethnic groups and nationalities in attendance, around 2 million visitors from more than 183 countries will return home, having participated in this singularly rigorous and peaceful event.

Series

Emergence of medicine for mass gatherings: lessons from the Hajj

Ziad A Memish, Gwen M Stephens, Robert Steffen, Qanta A Ahmed

Summary

Although definitions of mass gatherings (MG) vary greatly, they consist of large numbers of people attending an event at a specific site for a finite time. Examples of MGs include World Youth Day, the summer and winter Olympics, rock concerts, and political rallies. Some of the largest MGs are spiritual in nature. Among all MGs, the public health issues, associated with the Hajj (an annual pilgrimage to Mecca, Saudi Arabia) is clearly the best reported—probably because of its international or even intercontinental implications in terms of the spread of infectious disease. Hajj routinely attracts 2·5 million Muslims for worship. WHO's global health initiatives have converged with Saudi Arabia's efforts to ensure the wellbeing of pilgrims, contain infectious diseases, and reinforce global health security through the management of the Hajj. Both initiatives emphasise the importance of MG health policies guided by sound evidence and based on experience and the timeliness of calls for a new academic science-based specialty of MG medicine.

Global perspectives for prevention of infectious diseases associated with mass gatherings

Ibrahim Abubakar, Philippe Gautret, Gary W Brunette, Lucille Blumberg, David Johnson, Gilles Pomeroy, Ziad A Memish, Maurizio Barbeschi, Ali S Khan

Summary

We assess risks of communicable diseases that are associated with mass gatherings (MGs), outline approaches to risk assessment and mitigation, and draw attention to some key challenges encountered by organisers and participants. Crowding and lack of

sanitation at MGs can lead to the emergence of infectious diseases, and rapid population movement can spread them across the world. Many infections pose huge challenges to planners of MGs; however, these events also provide an opportunity to engage in public health action that will benefit host communities and the countries from which participants originate.

Medical Decision Making (MDM)

November/December 2011; 31 (6)

<http://mdm.sagepub.com/content/current>

[No relevant content]

Nature

Volume 480 Number 7378 pp413-578 22 December 2011

http://www.nature.com/nature/current_issue.html

Reviews

Cancer immunotherapy comes of age

Ira Mellman, George Coukos & Glenn Dranoff

Activating the immune system for therapeutic benefit in cancer has long been a goal in immunology and oncology. After decades of disappointment, the tide has finally changed due to the success of recent proof-of-concept clinical trials. Most notable has been the ability of the anti-CTLA4 antibody, ipilimumab, to achieve a significant increase in survival for patients with metastatic melanoma, for which conventional therapies have failed. In the context of advances in the understanding of how tolerance, immunity and immunosuppression regulate antitumour immune responses together with the advent of targeted therapies, these successes suggest that active immunotherapy represents a path to obtain a durable and long-lasting response in cancer patients.

Nature Medicine

December 2011, Volume 17 No 12

<http://www.nature.com/nm/index.html>

[Reviewed earlier]

Nature Reviews Immunology

January 2012 Vol 12 No 1

<http://www.nature.com/nri/journal/v11/n12/index.html>

Science and society

Vaccines targeting drugs of abuse: is the glass half-empty or half-full?

Kim D. Janda & Jennifer B. Treweek

p67 | doi:10.1038/nri3130

The advent of vaccines targeting drugs of abuse heralded a fundamentally different approach to treating substance-related disorders. In contrast to traditional pharmacotherapies for drug abuse, vaccines act by sequestering circulating drugs and terminating the drug-induced 'high' without inducing unwanted neuromodulatory effects. Drug-targeting vaccines have entered clinical evaluation, and although these vaccines

show promise from a biomedical viewpoint, the ethical and socioeconomic implications of vaccinating patients against drugs of abuse merit discussion within the scientific community.

New England Journal of Medicine

<http://content.nejm.org/current.shtml>

December 29, 2011 Vol. 365 No. 26

[No relevant content]

December 22, 2011 Vol. 365 No. 25

Perspective

Global Health: Facing a "Slow-Motion Disaster" — The UN Meeting on Noncommunicable Diseases

L. Rosenbaum and D. Lamas

Global Health: Stemming the Brain Drain — A WHO Global Code of Practice on International Recruitment of Health Personnel

A.L. Taylor, L. Hwenda, B.-I. Larsen, and N. Daulaire

OMICS: A Journal of Integrative Biology

<http://www.liebertonline.com/toc/omi/15/11>

Volume 15, Number 11

[No relevant content]

The Pediatric Infectious Disease Journal

December 2011 - Volume 30 - Issue 12 pp: 1019-1051,e225-e247

<http://journals.lww.com/pidj/pages/currenttoc.aspx>

[No relevant content]

Pediatrics

January 2012, VOLUME 129 / ISSUE 1

<http://pediatrics.aappublications.org/current.shtml>

Pediatrics Perspective

Overview of the Global Health Issues Facing Children

Sergio Augusto Cabral, Anna Tereza Soares de Moura, and Jay E. Berkelhamer

Pediatrics 2012; 129:1-3

Abstract

This first Pediatrics Perspectives column on global health joins the monthly rotation with other columns on medical history, graduate medical education, and medical student education. It makes good sense to add global health to the rotation. After all, the future of our world depends on the health and well-being of all its children. Medical history will be determined by the global health issues facing children today, and surely our education programs must broaden their content to include worldwide issues to meet the demands of future pediatric practice. It has been said by many pediatricians that any

disease found on this planet is no farther than a plane ride from your local hospital. Clearly, the world is a very small place for all its inhabitants, and every day, travel continues to bring us closer. Global Health Perspectives will bring issues to the readership that will stimulate our thinking about strategies and initiatives to improve child health in the broadest context. For our initial column, Drs Cabral and Soares de Moura have traced the recent history of global child health, sharing perspectives that should cause each of us to think about the future of humankind.

Pharmacoeconomics

January 1, 2012 - Volume 30 - Issue 1 pp: 1-81

<http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx>

[Reviewed earlier]

PLoS One

[Accessed 1 January 2012]

<http://www.plosone.org/article/browse.action;jsessionid=577FD8B9E1F322DAA533C413369CD6F3.ambra01?field=date>

Controlling the Spread of Disease in Schools

Benjamin J. Ridenhour, Alexis Braun, Thomas Teyrasse, David Goldman

PLoS ONE: Research Article, published 29 Dec 2011 10.1371/journal.pone.0029640

Abstract

Pandemic and seasonal infectious diseases such as influenza may have serious negative health and economic consequences. Certain non-pharmaceutical intervention strategies – including school closures – can be implemented rapidly as a first line of defense against spread. Such interventions attempt to reduce the effective number of contacts between individuals within a community; yet the efficacy of closing schools to reduce disease transmission is unclear, and closures certainly result in significant economic impacts for caregivers who must stay at home to care for their children. Using individual-based computer simulation models to trace contacts among schoolchildren within a stereotypical school setting, we show how alternative school-based disease interventions have great potential to be as effective as traditional school closures without the corresponding loss of workforce and economic impacts.

Attitudes toward and Uptake of H1N1 Vaccine among Health Care Workers during the 2009 H1N1 Pandemic

Joan M. Henriksen Hellyer, Aaron S. DeVries, Sarah M. Jenkins, Kandace A. Lackore, Katherine M. James, Jeanette Y. Ziegenfuss, Gregory A. Poland, Jon C. Tilburt

PLoS ONE: Research Article, published 22 Dec 2011 10.1371/journal.pone.0029478

Abstract

Background

Though recommended by many and mandated by some, influenza vaccination rates among health care workers, even in pandemics, remain below optimal levels. The objective of this study was to assess vaccination uptake, attitudes, and distinguishing characteristics (including doctor-nurse differences) of health care workers who did and did not receive the pandemic H1N1 influenza vaccine in late 2009.

Methodology/Principal Findings

In early 2010 we mailed a self-administered survey to 800 physicians and 800 nurses currently licensed and practicing in Minnesota. 1,073 individuals responded (cooperation rate: 69%). 85% and 62% of Minnesota physicians and nurses, respectively, reported being vaccinated. Accurately estimating the risk of vaccine side effects (OR 2.0; 95% CI 1.5–2.7), agreeing with a professional obligation to be vaccinated (OR 10.1; 95% CI 7.1–14.2), an ethical obligation to follow public health authorities' recommendations (OR 9.9; 95% CI 6.6–14.9), and laws mandating pandemic vaccination (OR 3.1; 95% CI 2.3–4.1) were all independently associated with receiving the H1N1 influenza vaccine.

Conclusions/Significance

While a majority of health care workers in one midwestern state reported receiving the pandemic H1N1 vaccine, physicians and nurses differed significantly in vaccination uptake. Several key attitudes and perceptions may influence health care workers' decisions regarding vaccination. These data inform how states might optimally enlist health care workers' support in achieving vaccination goals during a pandemic.

Community-Based Values for 2009 Pandemic Influenza A H1N1 Illnesses and Vaccination-Related Adverse Events

Tara A. Lavelle, Martin I. Meltzer, Achamyeleh Gebremariam, Kara Lamarand, Anthony E. Fiore, Lisa A. Prosser

PLoS ONE: Research Article, published 19 Dec 2011 10.1371/journal.pone.0027777

Abstract

Objective

To evaluate community-based values for avoiding pandemic influenza (A) H1N1 (pH1N1) illness and vaccination-related adverse events in adults and children.

Methods

Adult community members were randomly selected from a nationally representative research panel to complete an internet survey (response rate = 65%; n = 718). Respondents answered a series of time trade-off questions to value four hypothetical health state scenarios for varying ages (1, 8, 35, or 70 years): uncomplicated pH1N1 illness, pH1N1 illness-related hospitalization, severe allergic reaction to the pH1N1 vaccine, and Guillain-Barré syndrome. We calculated descriptive statistics for time trade-off amounts and derived quality adjusted life year losses for these events. Multivariate regression analyses evaluated the effect of scenario age, as well as respondent socio-demographic and health characteristics on time trade-off amounts.

Results

Respondents were willing to trade more time to avoid the more severe outcomes, hospitalization and Guillain-Barré syndrome. In our adjusted and unadjusted analyses, age of the patient in the scenario was significantly associated with time trade-off amounts (p-value<0.05), with respondents willing to trade more time to prevent outcomes in children versus adults. Persons who had received the pH1N1 vaccination were willing to trade significantly more time to avoid hospitalization, severe allergic reaction, and Guillain-Barré syndrome, controlling for other variables in adjusted analyses.(p-value<0.05)

Conclusions

Community members placed the highest value on preventing outcomes in children, compared with adults, and the time trade-off values reported were consistent with the severity of the outcomes presented. Considering these public values along with other decision-making factors may help policy makers improve the allocation of pandemic vaccine resources.

PLoS Medicine

(Accessed 1 January 2012)

<http://www.plosmedicine.org/article/browse.action?field=date>

[No new relevant content]

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

(Accessed 1 January 2012)

<http://www.pnas.org/content/early/recent>

[No new relevant content]

Science

23 December 2011 vol 334, issue 6063, pages 1593-1752

<http://www.sciencemag.org/current.dtl>

News

Breakthrough of the Year

HIV Treatment as Prevention

Jon Cohen

HIV/AIDS researchers have long debated whether antiretroviral drugs (ARVs) used to treat HIV-infected people might have a double benefit and cut transmission rates. To some it was obvious: ARVs reduce HIV levels, so individuals should be less infectious. Skeptics contended that this was unproven. Then in May of this year, the 052 clinical trial conducted by the HIV Prevention Trials Network (HPTN) reported that ARVs reduced the risk of heterosexual transmission by 96%. Because of HPTN 052's profound implications for the future response to the AIDS epidemic, Science has chosen it as its Breakthrough of the Year.

Science Translational Medicine

21 December 2011 vol 3, issue 114

<http://stm.sciencemag.org/content/mcurrent>

Research Articles

COMPUTATIONAL PHARMACOLOGY

Predicting Adverse Drug Events Using Pharmacological Network Models

Aurel Cami, Alana Arnold, Shannon Manzi, and Ben Reis

21 December 2011: 114ra127

Abstract

Early and accurate identification of adverse drug events (ADEs) is critically important for public health. We have developed a novel approach for predicting ADEs, called predictive pharmacosafety networks (PPNs). PPNs integrate the network structure formed by known drug-ADE relationships with information on specific drugs and adverse events to predict likely unknown ADEs. Rather than waiting for sufficient post-market evidence to accumulate for a given ADE, this predictive approach relies on leveraging existing, contextual drug safety information, thereby having the potential to identify

certain ADEs earlier. We constructed a network representation of drug-ADE associations for 809 drugs and 852 ADEs on the basis of a snapshot of a widely used drug safety database from 2005 and supplemented these data with additional pharmacological information. We trained a logistic regression model to predict unknown drug-ADE associations that were not listed in the 2005 snapshot. We evaluated the model's performance by comparing these predictions with the new drug-ADE associations that appeared in a 2010 snapshot of the same drug safety database. The proposed model achieved an AUROC (area under the receiver operating characteristic curve) statistic of 0.87, with a sensitivity of 0.42 given a specificity of 0.95. These findings suggest that predictive network methods can be useful for predicting unknown ADEs.

Tropical Medicine & International Health

January 2012 Volume 17, Issue 1 Pages 1–141

[http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1365-3156/currentissue](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-3156/currentissue)

Inclusive health

Malcolm MacLachlan, Chapal Khasnabis and Hasheem Mannan

Article first published online: 7 SEP 2011 | DOI: 10.1111/j.1365-3156.2011.02876.x

[Free full text]

Abstract

We propose the concept of Inclusive Health to encapsulate the Health for All ethos; to build on the rights-based approach to health; to promote the idea of inclusion as a verb, where a more proactive approach to addressing distinctive and different barriers to inclusion is needed; and to recognise that new initiatives in human resources for health can offer exciting and innovative ways of healthcare delivery. While Inclusive Education has become a widely recognised and accepted concept, Health for All is still contested, and new thinking is required to develop its agenda in line with contemporary developments. Inclusive Health refers both to who gets health care and to who provides it; and its ethos resonates strongly with Jefferson's assertion that 'there is nothing more unequal, than the equal treatment of unequal people'. We situate the timeliness of the Inclusive Health concept with reference to recent developments in the recognition of the rights of people with disability, in the new guidelines for community-based rehabilitation and in the World Report on Disability. These developments offer a more inclusive approach to health and, more broadly, its inter-connected aspects of wellbeing. A concept which more proactively integrates United Nations conventions that recognise the importance of difference – disability, ethnicity, gender, children – could be of benefit for global healthcare policy and practice.

Vaccine

<http://www.sciencedirect.com/science/journal/0264410X>

Volume 30, Issue 3 pp. 499-684 (11 January 2012)

Review

[Devices for intradermal vaccination](#)

Pages 523-538

Elsa E. Kis, Gerhard Winter, Julia Myschik

Abstract

New insights in vaccine development, the need for safe, economic and efficient vaccine administration and the increasing mechanistic knowledge of immune responses induced by targeting the intradermal layers of the skin have all driven the engineering of devices for intradermal vaccination. In this review we highlight different delivery devices that make the epidermal and dermal layers of the skin accessible for vaccine administration. Depending on the device the desired vaccine can be applied either as a liquid formulation or as solid, powdered vaccine particles. The process of intradermal injection employs micron-sized needles that are inserted 1.5 mm perpendicularly into the skin, and which inject approximately 100–200 µl of a liquid vaccine formulation into the dermal skin layers. Tattoo devices, on the other hand, can be used to deliver liquid vaccine formulations into the dermal layer of the skin by the use of oscillating needles. Microneedle arrays are made of vaccine-coated solid microneedles or biodegradable microneedles. These are inserted into the dermal layers of the skin where either the vaccine coating is dissolved, or the microneedle itself dissolves in place. Jet-injectors operate by generating a high pressured stream, which flushes the liquid vaccine formulation into the deeper skin layers. Delivery devices using liquid vaccine formulations are advantageous, as established vaccine formulations can be used as provided without the need for reformulation. However, approaches that deliver vaccines in a solid form may also prove to be promising. One such method is the ballistic approach, in which solid vaccine particles or vaccine-coated gold particles are accelerated towards the skin by needle-free devices, so that the particles are deposited in the epidermal and dermal layers of the skin. These various delivery devices are explored in this review with regard to their delivery mechanism and ease of handling, their efficacy in clinical trials and their suitability for practical use.

Regular Papers

Effectiveness of rotavirus vaccines in preventing cases and hospitalizations due to rotavirus gastroenteritis in Navarre, Spain

Pages 539-543

Jesús Castilla, Xabier Beristain, Víctor Martínez-Artola, Ana Navascués, Manuel García Cenoz, Nerea Álvarez, Isabel Polo, Ana Mazón, Alberto Gil-Setas, Aurelio Barricarte

Abstract

Two rotavirus vaccines have been available since 2006. This study evaluates the effectiveness of these vaccines using a test-negative case–control design in Navarre, Spain. We included children 3–59 months of age who sought medical care for gastroenteritis and for whom stool samples were taken between January 2008 and June 2011. About 9% had received the pentavalent vaccine (RotaTeq) and another 8% received the monovalent vaccine (Rotarix). Cases were the 756 children with confirmed rotavirus and controls were the 6036 children who tested negative for rotavirus. Thirty-five percent of cases and 9% of controls had required hospitalization ($p < 0.0001$). The adjusted effectiveness of complete vaccination was 78% (95% CI: 68–85%) in preventing rotavirus gastroenteritis and 83% (95% CI: 65–93%) in preventing hospitalization for rotavirus gastroenteritis. No differences between the two vaccines were detected ($p = 0.4523$). Both vaccines were highly effective in preventing cases and hospital admissions in children due to rotavirus gastroenteritis.

Cost-effectiveness of vaccination against herpes zoster in adults aged over 60 years in Belgium

Pages 675-684

Joke Bilcke, Christiaan Marais, Benson Ogunjimi, Lander Willem, Niel Hens, Philippe Beutels

Abstract

Aim

To assess the cost-effectiveness of vaccinating all or subgroups of adults aged 60 to 85 years against herpes zoster.

Methods

A deterministic compartmental static model was developed (in freeware R), in which cohorts can acquire herpes zoster according to their age in years. Surveys and database analyses were conducted to obtain as much as possible Belgian age-specific estimates for input parameters. Direct costs and Quality-Adjusted Life-Year (QALY) losses were estimated as a function of standardised Severity Of Illness (SOI) scores (i.e. as a function of the duration and severity of herpes zoster disease).

Results

Uncertainty about the average SOI score for a person with herpes zoster, the duration of protection from the vaccine, and the population that can benefit from the vaccine, exerts a major impact on the results: under assumptions least in favour of vaccination, vaccination is not cost-effective (i.e. incremental cost per QALY gained >€48,000 for all ages considered) at the expected vaccine price of €90 per dose. At the same price, but under assumptions most in favour of vaccination, vaccination is found to be cost-effective (i.e. incremental cost per QALY gained <€5500 for all ages considered). Vaccination of age cohort 60 seems more cost-effective than vaccination of any older age cohort in Belgium.

Discussion

If the vaccine price per dose drops to €45, HZ vaccination of adults aged 60–64 years is likely to be cost-effective in Belgium, even under assumptions least in favour of vaccination. Unlike previous studies, our analysis acknowledged major methodological and model uncertainties simultaneously and presented outcomes for 26 different target ages at which vaccination can be considered (ages 60–85).

Vaccine

Volume 30, Issue 2 pp. 103-498 (5 January 2012)

Editorial

[The re-emergence of measles in developed countries: Time to develop the next-generation measles vaccines?](#)

Pages 103-104

Gregory A. Poland, Robert M. Jacobson

[No abstract available]

Brief Reports

[Vaccine shortages and suspect online pharmacy sellers](#)

Pages 105-108

Bryan A. Liang, Tim K. Mackey

Abstract

Vaccines represent half the products on the FDA Biologics Product Shortages list. As a result, providers and patients may purchase them online, a process rife with patient safety risks. We examined vaccine online availability by assessing up to 5 identified online sellers. We determined if sites were accredited by the National Association of Boards of Pharmacy (NABP) VIPPS program, listed as US or international, employed

social media linking to suspect online pharmacies, and if they were on the NABP Not Recommended list. All vaccines were advertised by online pharmacies and through data aggregation and social media sites, none were VIPPS-accredited, and most were on the NABP Not Recommended list. We found some online sellers advertising vaccines as over-the-counter. We extended our analysis to WHO Essential Medicines List vaccines and found all are also available online from suspect, non-VIPPS accredited sellers. Stakeholders should be aware of these online patient safety dangers.

Reviews

New insights in mucosal vaccine development

Pages 142-154

Vincent Pavot, Nicolas Rochereau, Christian Genin, Bernard Verrier, Stéphane Paul

Abstract

Mucosal surfaces are the major entrance for infectious pathogens and therefore mucosal immune responses serve as a first line of defence. Most current immunization procedures are obtained by parenteral injection and only few vaccines are administered by mucosal route, because of its low efficiency. However, targeting of mucosal compartments to induce protective immunity at both mucosal sites and systemic level represents a great challenge. Major efforts are made to develop new mucosal candidate vaccines by selecting appropriate antigens with high immunogenicity, designing new mucosal routes of administration and selecting immune-stimulatory adjuvant molecules. The aim of mucosal vaccines is to induce broad potent protective immunity by specific neutralizing antibodies at mucosal surfaces and by induction of cellular immunity. Moreover, an efficient mucosal vaccine would make immunization procedures easier and be better suited for mass administration. This review focuses on contemporary developments of mucosal vaccination approaches using different routes of administration.

Regular Papers

Improving low coverage of child immunization in rural hard-to-reach areas of Bangladesh: Findings from a project using multiple interventions

Pages 168-179

Md. Jasim Uddin, Nirod Chandra Saha, Ziaul Islam, Iqbal Ansary Khan, Shamsuzzaman, M.A. Quaiyum, Tracey Perez Koehlmoos

Abstract

The study was conducted to assess the impact of combined interventions to improve the child immunization coverage in rural hard-to-reach areas of Bangladesh. The valid coverage increased at endline compared to baseline in the study areas, and the difference of the increase was highly significant ($p < 0.001$). The findings also showed that the number of drop-outs, left-outs, and invalid doses decreased at endline compared to baseline in the study areas, and the difference was also highly significant ($p < 0.001$). The immunization coverage improved significantly in all the four study sub-districts that received interventions, although the relative contribution of each intervention is unknown. The interventions can be implemented in all other hard-to-reach areas of Bangladesh and other countries which are facing similar challenges.

Birth order and private voluntary immunization—A study of 110,902 children

Pages 442-447

Natalie Gavrielov-Yusim, Erez Battat, Lily Neumann, Michael Friger, Ran D. Balicer

Abstract

Background

Introduction of new private, voluntary immunizations often results in low vaccine uptake among certain sub-groups within the population. Revealing factors associated with underimmunization is crucial in vaccine endorsement and distribution.

Objective

Our goal was to investigate the effect of child's birth order on private voluntary varicella vaccination.

Methods

A nested case-control study was conducted on a cohort of 110,902 Israeli children under the age of 5 years. We compared social and demographic factors of immunized and unimmunized participants. Logistic regression models were built to examine the association between birth order and vaccination, controlling for child's age, gender, country of birth, ethnicity, parents' country of birth, area of residence, and socioeconomic status (SES).

Results

Ethnicity had the highest association with varicella immunization status. The odds of vaccination in the general Jewish and Ultra-Orthodox Jewish populations were 25.55- (95%CI:20.13;32.42) and 15.04- (95%CI:10.18;22.22) times the odds in Arab population, respectively. Child's birth order was inversely related to vaccination status and presented a nonlinear exposure-response relationship. This relationship was maintained in different ethnicity and SES groups. Child's birth order was associated with vaccination differently in large (>3 siblings) and small to average-sized sibships (≤ 3 siblings). Other parameters associated with vaccination were child's and parents' country of origin, area of residence and SES.

Conclusions

Birth order is an independent risk factor for underimmunization, associated with child's vaccination status beyond economic, social, and demographic parental characteristics.

Knowledge, attitudes, and beliefs about seasonal influenza and H1N1 vaccinations in a low-income, public health clinic population

Pages 454-458

Matthew D. Redelings, Jennifer Piron, Lisa V. Smith, Amy Chan, Julia Heinzerling, Kathleen M. Sanchez, Dalia Bedair, Mirna Ponce, Tony Kuo

Abstract

Objective

The Public Health Center Vaccine Survey (PHCVS) examines the knowledge, attitudes, and beliefs about seasonal influenza and H1N1 vaccinations in a largely low-income, urban, public health clinic population in Los Angeles County, USA.

Design

A cross-sectional survey of vulnerable individuals at risk for severe influenza infection was conducted in one of the nation's largest local public health jurisdictions.

Subjects

A total of 1541 clinic patients were recruited in the waiting rooms of five large public health centers in Los Angeles County from June to August, 2010.

Results

Among prospective respondents who met eligibility criteria, 92% completed the survey. The majority was black or Latino and most were between the ages of 18 and 44 years. More than half were unemployed; two-thirds had no health insurance; and nearly one-half reported having a high school education or less. About one-fifth reported they had received the H1N1 vaccine during the previous flu season. In comparative analyses,

negative beliefs about vaccine safety and efficacy were highly predictive of H1N1 vaccination. Blacks were less likely than non-black respondents to report receiving the H1N1 vaccine (OR = 0.7, 95% CI = 0.6–1.0). Blacks were also less likely than other respondents to agree that vaccines can prevent disease (OR = 0.4, 95% CI = 0.3–0.5), that vaccines are safe (OR = 0.5, 95% CI = 0.4–0.6), and that they trust doctors/clinicians who recommend vaccines (OR = 0.5, 95% CI = 0.4–0.7).

Conclusions

Study findings provide a useful risk profile of vulnerable groups in Los Angeles County, which may be generalizable to other urban jurisdictions in the United States. They also describe real world situations that can be used to forecast potential challenges that vaccine beliefs may pose to national as well as local influenza pandemic planning and response, especially for communities with limited access to these preventive services

Vaccine

Articles in Press

Evidence-based decision making for vaccines: The need for an ethical foundation

In Press, Corrected Proof, Available online 21 December 2011

Robert I. Field, Arthur L. Caplan

Abstract

Evidence-based decision making (EBDM) is a tool to assess the value of medical interventions by weighing costs and health outcomes that has increasingly been applied to vaccines. However, many of the ethical considerations that support EBDM when used to evaluate therapeutic care do not readily translate to prevention. This mismatch can result in policy decisions that produce unanticipated negative consequences, including public resistance. In its emphasis on quantifiable outcomes, EBDM invokes the ethical principle of rule-utilitarianism, which values the optimal long-run balance of benefit over harm. Vaccines raise a number of competing ethical concerns in ways that individual medical treatments do not. They rely on widespread compliance for effectiveness, which can limit individual autonomy, emphasize population over individual effects, which can obscure the imperative of beneficence to help the vulnerable, require a just allocation process within populations, and sometimes challenge strong social norms. For EBDM to effectively guide vaccine policy makers, such as the Advisory Committee on Immunization Practices (ACIP) in the United States, an ethical foundation is needed that systematically considers all relevant values and transparently places vaccination recommendations in the context of social norms and individual concern

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