

## Center for Vaccine Ethics and Policy

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### **Vaccines: The Week in Review 24 November 2012 Center for Vaccine Ethics & Policy (CVEP)**

*This weekly summary targets news, events, announcements, articles and research in the global vaccine 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 recommends seasonal influenza vaccination to pregnant women as the highest priority**

"In an updated position paper, published in the Weekly Epidemiological Record today, WHO recommends that countries considering the initiation or expansion of seasonal influenza vaccination programmes give the highest priority to pregnant women. Additional risk groups to be considered for vaccination, in no particular order of priority, are: children aged 6-59 months; the elderly; individuals with specific chronic medical conditions; and healthcare workers."

<http://www.who.int/immunization/en/>

The **Weekly Epidemiological Record (WER) for 23 November 2012**, vol. 87, 47 (pp. 461-476) includes: Vaccines against influenza - WHO position paper - November 2012

<http://www.who.int/entity/wer/2012/wer8747.pdf>

**The FDA said it approved Flucelvax, described as the first seasonal influenza vaccine licensed in the United States produced using cultured animal cells, instead of fertilized chicken eggs.** Flucelvax is approved to prevent seasonal influenza in people ages 18 years and older. The manufacturing process for Flucelvax is similar to the egg-based production method, but a significant difference is that the virus strains included in the vaccine are grown in animal cells of mammalian origin instead of in eggs. Cell culture technology has already been in use for several decades to produce other U.S. licensed vaccines. Karen Midthun, M.D., director of the FDA's Center for Biologics Evaluation and Research, said, "Today's approval represents the culmination of efforts to develop a seasonal influenza vaccine using cell

culture as an alternative to the egg-based process." Flucelvax is manufactured by Novartis Vaccines and Diagnostics GmbH, Marburg, Germany.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm328982.htm>

**The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the granting of a marketing authorisation for Bexsero, a new Novartis vaccine intended for the immunisation of individuals over two months of age against invasive meningococcal disease caused by Neisseria meningitidis group B.**

There is currently no authorised vaccine available in the European Union (EU) for bacterial meningitis caused by Neisseria meningitidis group B...In Europe, group B is the most prevalent meningococcal serogroup, with 3,406-4,819 cases reported annually between 2003 and 2007, according to a surveillance report published by the European Centre for Disease Prevention and Control....There are currently some geographical regions within the EU with higher incidence rates, mainly in Belgium, Ireland, Spain and the United Kingdom...The impact of invasive disease in different age groups as well as the variability of antigen epidemiology for group-B strains in different geographical areas should be considered when vaccinating. Vaccination with Bexsero should be in accordance with official recommendations applicable in the Member States. The CHMP's opinion on Bexsero will now be sent to the European Commission for the granting of a marketing authorisation.

[http://www.ema.europa.eu/ema/index.jsp?](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/11/news_detail_001656.jsp&mid=WC0b01ac058004d5c1)

[curl=pages/news\\_and\\_events/news/2012/11/news\\_detail\\_001656.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/11/news_detail_001656.jsp&mid=WC0b01ac058004d5c1)

**Update: Polio this week - As of 20 Nov 2012**

Global Polio Eradication Initiative

<http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx>

*[Editor's Extract]*

- This week, immunization campaigns are being implemented in all three remaining endemic countries, Nigeria, Pakistan and Afghanistan. Focus continues to be on urgently boosting immunity levels in known high-risk areas.

**Afghanistan**

- Three new WPV cases were reported in the past week (one WPV1 from Kandahar and two WPV1s from Hilmand), bringing the total number of WPV cases for 2012 to 30. The WPV1 from Kandahar is the most recent case in the country and had onset of paralysis on 28 October.

- Supplementary immunization activities (SIAs) are taking place this week (19-21 November), with the next activity planned for 01-06 December.

- The current campaign is being conducted in border areas with Pakistan, and uses a combination of trivalent OPV and bivalent OPV (depending on the area, in response either to recent WPV1 cases in the area, or to detection of a circulating vaccine-derived poliovirus type 2 outbreak – cVDPV2 – across the border in Pakistan).

- The Technical Advisory Group (TAG) is meeting next week in Kabul, to review the impact of the national polio emergency action plan and discuss additional tactics to address on-going immunity gaps in known high-risk districts.

**Nigeria**

- Four new WPV cases were reported in the past week (one WPV1 each from Jigawa, Kaduna, Kano and Katsina), bringing the total number of WPV cases for 2012 to 104. The WPV1 from Kaduna is the most recent case in the country and had onset of paralysis on 30 October.

#### ***Horn of Africa***

- Efforts are continuing to stop an ongoing cVDPV2 outbreak in Kenya and parts of Somalia (in a Somali refugee camp in Dadaab, Kenya, and Kismayo, south-central Somalia).  
- Immunizations of older age groups have taken place in Dadaab. In Somalia, campaigns have been conducted in border areas with Kenya and Ethiopia, and in some areas of central Somalia (access allowing).

#### **WHO: Global Alert and Response (GAR) - *Disease Outbreak News***

##### **- Announcement: WHO to change the way it reports H5N1 cases**

Henceforward, WHO will publish information on human cases with H5N1 avian influenza infection on a monthly basis on the Influenza webpage:

[Influenza at human-animal interface - Monthly Risk Assessment Summary](#)

Cases of human infection with H5N1 will only be reported on Disease Outbreak News for events that are unusual or associated with potential increased risks.

Member States will be continued to require to report information on every sporadic case of H5N1 human infection or novel influenza virus infection to WHO as per Article 6 of the International Health Regulations (2005).

##### **Most recent news items**

- Ebola in Uganda [23 November 2012](#)
- Novel coronavirus infection – update [23 November 2012](#)
- Marburg haemorrhagic fever in Uganda – update [23 November 2012](#)
- Yellow fever in Sudan – update [22 November 2012](#)

<http://www.who.int/csr/don/en/index.html>

#### **Conferences/Reports/Research/Analysis/Book Watch**

*Vaccines: 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](mailto:david.r.curry@centerforvaccineethicsandpolicy.org)

[No new content]

#### **Journal Watch**

*Vaccines: 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](mailto:david.r.curry@centerforvaccineethicsandpolicy.org)*

### **American Journal of Public Health**

Volume 102, Issue 12 (December 2012)

<http://ajph.aphapublications.org/toc/ajph/current>

[Reviewed earlier; No relevant content]

### **Annals of Internal Medicine**

20 November 2012, Vol. 157. No. 10

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

[No relevant content]

### **BMC Public Health**

(Accessed 24 November 2012)

<http://www.biomedcentral.com/bmcpublichealth/content>

[No new relevant content]

### **British Medical Bulletin**

Volume 103 Issue 1 September 2012

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

[Reviewed earlier]

### **British Medical Journal**

24 November 2012 (Vol 345, Issue 7884)

<http://www.bmj.com/content/345/7884>

#### **[Time for global action on fake and substandard drugs](#)**

BMJ 2012;345:e7917 (Published 21 November 2012)

*Excerpt*

"In an article this week a self defined "diverse group of authors from the health professions, health charities, legal and medical academia, and former or current government officials in health" present us with a troubling paradox: the world currently has tighter laws to tackle fake tobacco products than it does to tackle fake drugs (doi:[10.1136/bmj.e7381](https://doi.org/10.1136/bmj.e7381)). At the moment, as they explain, there are laws that promote an open global medicines trade but no binding international health law on drug safety. The result is that fake and substandard drugs continue to harm and kill people around the world, affecting both proprietary and generic drugs, and haunting rich countries as well as poor. As Andrew Jack explains (doi:[10.1136/bmj.e7836](https://doi.org/10.1136/bmj.e7836)), the rapid growth of unregulated internet sales of drugs has raised the stakes even further. In the accompanying podcast, Amir Attiran emphasises the absurd situation by which trading fake medicines is currently legal under international law, and Sania Nishtar highlights worryingly weak pharmacovigilance systems in Pakistan ([www.bmj.com/multimedia](http://www.bmj.com/multimedia)).

Why the lack of progress on this globally damaging health problem? There's no simple answer to what is clearly a complex problem, but the authors suggest that the main barriers have been the lack of an internationally agreed terminology and a focus in law on commercial interests rather than public health..."

### **[Faking it](#)**

BMJ 2012;345:e7836 (Published 20 November 2012)

[Analysis](#)

[Podcast](#)

### **[How to achieve international action on falsified and substandard medicines](#)**

BMJ 2012;345:e7381 (Published 13 November 2012)

[Analysis](#)

[Podcast](#)

[Feature](#)

[Press release](#)

### **[Commentary: Substandard medicines are the priority for neglected tropical diseases](#)**

BMJ 2012;345:e7518 (Published 14 November 2012)

[Analysis](#)

## **Bulletin of the World Health Organization**

Volume 90, Number 11, November 2012, 793-868

<http://www.who.int/bulletin/volumes/90/11/en/index.html>

[Reviewed earlier]

## **Cost Effectiveness and Resource Allocation**

(Accessed 24 November 2012)

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

[No new relevant content]

## **Emerging Infectious Diseases**

Volume 18, Number 12—December 2012

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

[No relevant content]

## **Eurosurveillance**

Volume 17, Issue 47, 22 November 2012

<http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678>

[No new relevant content]

## **Global Health Governance**

Volume V, Issue 2: Spring 2012

<http://blogs.shu.edu/ghg/2012/06/22/volume-v-issue-2-spring-2012/>

[Reviewed earlier]

## **Globalization and Health**

[Accessed 24 November 2012]

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

[No new relevant content]

## **Health Affairs**

November 2012; Volume 31, Issue 11

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

*Theme: ACOs, Medical Homes, Nursing, Costs and Quality*

[No specific relevant content on vaccines/immunization]

## **Health and Human Rights**

Vol 14, No 1 (2012)

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

[Reviewed earlier]

## **Health Economics, Policy and Law**

Volume7 / Issue04 / October 2012, pp 383 - 384

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

***Special Issue: End of Life Care and Evaluation***

[No specific relevant content on vaccines/immunization]

## **Health Policy and Planning**

Volume 27 Issue 7 October 2012

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

[Reviewed earlier]

***Advance Access***

<http://heapol.oxfordjournals.org/content/early/2012/11/21/heapol.czs123.abstract>

**Lessons learned in shaping vaccine markets in low-income countries: a review of the vaccine market segment supported by the GAVI Alliance**

Shawn A.N. Gilchrist and [Angeline Nanni](#)

*Abstract*

**Objectives** The Global Alliance for Vaccines and Immunization (GAVI) anticipated that growing demand for new vaccines could sufficiently impact the vaccines market to allow low-income countries (LICs) to self-finance new vaccines. But the time required to lower vaccine prices was underestimated and the amount that prices would decline overestimated. To better understand how prices in the LIC vaccine market can be impacted, the vaccine market was retrospectively examined.

**Design** GAVI archives and the published literature on the vaccine markets in LICs were reviewed for the purpose of identifying GAVI's early assumptions for the evolution of vaccine prices, and contrasting these retrospectively with actual outcomes.

**Results** The prices in Phases I and II of GAVI-supported vaccines failed to decline to a desirable level within a projected 5-year timeframe. GAVI-eligible countries were unable to

sustain newly introduced vaccines without prolonged donor support. Two key lessons can be applied to future vaccine market-shaping strategies: (1) accurate demand forecasting together with committed donor funding can increase supply to the LIC vaccines market, but even greater strides can be made to increase the certainty of purchase; and (2) the expected time to lower prices took much longer than 5 years; market competition is inherently linked to the development time for new vaccines—a minimum of 5–10 or more years. Other factors that can lower vaccine prices include: large-scale production or alternate financing mechanisms that can hasten vaccine price maturation.

**Conclusions** The impacts of competition on vaccine prices in the LIC new-vaccines market occurred after almost 10 years. The time for research and development, acquisition of technological know-how and to scale production must be accounted for to more accurately predict significant declines on vaccine prices. Alternate financing mechanisms and the use of purchase agreements should also be considered for lowering prices when planning new vaccine introductions.

### **Human Vaccines & Immunotherapeutics** (formerly Human Vaccines)

Volume 8, Issue 11 November 2012

<http://www.landesbioscience.com/journals/vaccines/toc/volume/8/issue/11/>

#### **Special Issue: DNA Vaccines**

[Reviewed earlier]

### **Infectious Diseases of Poverty**

2012, 1

<http://www.idpjournal.com/content>

[Accessed 24 November 2012]

[No new relevant content]

### **International Journal of Infectious Diseases**

December 2012, Vol. 16, No. 12

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

[Reviewed earlier]

### **JAMA**

November 21, 2012, Vol 308, No. 19

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

[No relevant content]

### **Journal of Health Organization and Management**

Volume 26 issue 6 - Published: 2012

<http://www.emeraldinsight.com/journals.htm?issn=1477-7266&show=latest>

[Reviewed earlier; No relevant content]

**Journal of Infectious Diseases**

Volume 206 Issue 12 December 15, 2012

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

[No relevant content]

**Journal of Global Infectious Diseases (JGID)**

July-September 2012

Volume 4 | Issue 3 Page Nos. 139-186

<http://www.jgid.org/currentissue.asp?sabs=n>

[Reviewed earlier]

**Journal of Medical Ethics**

December 2012, Volume 38, Issue 12

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

[No relevant content]

**Journal of Medical Microbiology**

December 2012; 61 (Pt 12)

<http://jmm.sgmjournals.org/content/current>

[Reviewed earlier; No relevant content]

**Journal of the Pediatric Infectious Diseases Society (JPIDS)**

Volume 1 Issue 4 December 2012

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

[Reviewed earlier]

**The Lancet**

Nov 24, 2012 Volume 380 Number 9856 p1791 – 1880 e11

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

[No relevant content]

**The Lancet Infectious Disease**

Dec 2012 Volume 12 Number 12 p897 - 984

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

**Review****Strategies to increase responsiveness to hepatitis B vaccination in adults with HIV-1**

Jennifer A Whitaker, Nadine G Roupheal, Srilatha Edupuganti, Lilin Lai, Mark J Mulligan

**Summary**

HIV and hepatitis B virus co-infection leads to substantially increased morbidity and mortality compared with either infection alone. Immunisation with hepatitis B virus vaccine is the most effective way to prevent the infection in people with HIV; however, these patients have decreased vaccine responses and a short duration of protection compared with

immunocompetent individuals. Control of HIV replication with highly active antiretroviral therapy and increased CD4 cell counts are associated with improved immune responses to hepatitis B vaccination. New vaccination strategies, such as increased vaccine dose, use of the intradermal route, and addition of adjuvants, could improve response rates in adults with HIV.

### **Medical Decision Making (MDM)**

September–October 2012; 32 (5)

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

[Reviewed earlier]

### **The Milbank Quarterly**

*A Multidisciplinary Journal of Population Health and Health Policy*

September 2012 Volume 90, Issue 3 Pages 417–629

<http://onlinelibrary.wiley.com/doi/10.1111/milq.2012.90.issue-3/issuetoc>

[Reviewed earlier; No relevant content]

### **Nature**

Volume 491 Number 7425 pp495-632 22 November 2012

[http://www.nature.com/nature/current\\_issue.html](http://www.nature.com/nature/current_issue.html)

[No relevant content]

### **Nature Immunology**

December 2012, Volume 13 No 12 pp1129-1221

<http://www.nature.com/ni/journal/v13/n11/index.html>

[No relevant content]

### **Nature Medicine**

November 2012, Volume 18 No 11 pp1593-1715

<http://www.nature.com/nm/journal/v18/n11/index.html>

[Reviewed earlier; Reviewed earlier]

### **Nature Reviews Immunology**

November 2012 Vol 12 No 11

<http://www.nature.com/nri/journal/v12/n11/index.html>

[Reviewed earlier; No relevant content]

### **New England Journal of Medicine**

November 22, 2012 Vol. 367 No. 21

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

[No relevant content]

### **OMICS: A Journal of Integrative Biology**

November 2012, 16(11)

<http://online.liebertpub.com/toc/omi/16/11>

[Reviewed earlier ; No relevant content]

### **The Pediatric Infectious Disease Journal**

November 2012 - Volume 31 - Issue 11 pp: 1107-1138,e189-e231

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

[Reviewed earlier; No relevant content]

### **Pediatrics**

November 2012, VOLUME 130 / ISSUE 5

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

[Reviewed earlier]

### **Pharmacoeconomics**

December 1, 2012 - Volume 30 - Issue 12 pp: 1097-1214

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

[Reviewed earlier; No relevant content]

### **PLoS One**

[Accessed 24 November 2012]

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

#### **[Longitudinal Investigation of Public Trust in Institutions Relative to the 2009 H1N1 Pandemic in Switzerland](#)**

Adrian Bangerter, Franciska Krings, Audrey Mouton, Ingrid Gilles, Eva G. T. Green, Alain Clémence

PLoS ONE: Research Article, published 21 Nov 2012 10.1371/journal.pone.0049806

#### *Abstract*

#### Background

The 2009 H1N1 pandemic left a legacy of mistrust in the public relative to how outbreaks of emerging infectious diseases are managed. To prepare for future outbreaks, it is crucial to explore the phenomenon of public trust in the institutions responsible for managing disease outbreaks. We investigated the evolution of public trust in institutions during and after the 2009 pandemic in Switzerland. We also explored respondents' perceptions of the prevention campaign and the roles of the government and media.

#### Methodology/Principal Findings

A two-wave longitudinal survey was mailed to 2,400 members of the Swiss public. Wave 1 was in Spring 2009. Wave 2 was in Spring 2010. Six hundred and two participants responded in both waves. Participants indicated moderate to high levels of trust in medical organizations, the WHO, the Swiss government, the pharmaceutical industry, and the EU. On the other hand, trust in the media was low. Moreover, trust in almost all institutions decreased over time. Participants

were satisfied with the amount of information received and indicated having followed official recommendations, but widespread concerns about the vaccine were evident. A large majority of participants agreed the vaccine might have unknown or undesirable side effects. Perceptions of the government's and the media's role in handling the outbreak were characterized by a substantial degree of skepticism and mistrust.

#### Conclusions/Significance

Results show clear patterns of skepticism and mistrust on the part of the public relative to various institutions and their actions. Results underscore the importance of systematically investigating trust of the public relative to epidemics. Moreover, studies investigating the evolution of the public's memories of the pandemic over the coming years may be important to understand reactions to future pandemics. A systematic research program on trust can inform public health communication campaigns, enabling tailored communication initiatives.

#### **Economic Burden of Human Papillomavirus-Related Diseases in Italy**

Gianluca Baio, Alessandro Capone, Andrea Marcellusi, Francesco Saverio Mennini, Giampiero Favato

PLoS ONE: Research Article, published 21 Nov 2012 10.1371/journal.pone.0049699

#### *Abstract*

##### Introduction

Human papilloma virus (HPV) genotypes 6, 11, 16, and 18 impose a substantial burden of direct costs on the Italian National Health Service that has never been quantified fully. The main objective of the present study was to address this gap: (1) by estimating the total direct medical costs associated with nine major HPV-related diseases, namely invasive cervical cancer, cervical dysplasia, cancer of the vulva, vagina, anus, penis, and head and neck, anogenital warts, and recurrent respiratory papillomatosis, and (2) by providing an aggregate measure of the total economic burden attributable to HPV 6, 11, 16, and 18 infection.

##### Methods

For each of the nine conditions, we used available Italian secondary data to estimate the lifetime cost per case, the number of incident cases of each disease, the total economic burden, and the relative prevalence of HPV types 6, 11, 16, and 18, in order to estimate the aggregate fraction of the total economic burden attributable to HPV infection.

##### Results

The total direct costs (expressed in 2011 Euro) associated with the annual incident cases of the nine HPV-related conditions included in the analysis were estimated to be €528.6 million, with a plausible range of €480.1–686.2 million. The fraction attributable to HPV 6, 11, 16, and 18 was €291.0 (range €274.5–315.7 million), accounting for approximately 55% of the total annual burden of HPV-related disease in Italy.

##### Conclusions

The results provided a plausible estimate of the significant economic burden imposed by the most prevalent HPV-related diseases on the Italian welfare system. The fraction of the total direct lifetime costs attributable to HPV 6, 11, 16, and 18 infections, and the economic burden of noncervical HPV-related diseases carried by men, were found to be cost drivers relevant to the making of informed decisions about future investments in programmes of HPV prevention.

#### **PLoS Medicine**

(Accessed 24 November 2012)

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

## **The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials**

Charles Weijer, Jeremy M. Grimshaw, Martin P. Eccles, Andrew D. McRae, Angela White, Jamie C. Brehaut, Monica Taljaard, Ottawa Ethics of Cluster Randomized Trials Consensus Group published 20 Nov 2012

doi:10.1371/journal.pmed.1001346

### *Summary Points*

- In cluster randomized trials (CRTs), the units of allocation, intervention, and outcome measurement may differ within a single trial. As a result of the unique design of CRTs, the interpretation of existing research ethics guidelines is complicated.
- The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials aims to provide researchers and research ethics committees (RECs) with detailed guidance on the ethical design, conduct, and review of CRTs.
- A five-year mixed methods research project explored the ethical challenges of CRTs. Empirical studies documented the reporting of ethical issues in published CRTs, interviewed experienced trialists, and surveyed trialists and REC chairs. The ethical issues identified were explored in a series of background papers that provided detailed ethical analyses and policy options, and a panel of experts using a systematic process developed a consensus statement.
- The Ottawa Statement sets out 15 recommendations for the ethical design and conduct of CRTs. The recommendations provide guidance on the justification of a cluster randomized design, the need for REC review, the identification of research participants, obtaining informed consent, the role of gatekeepers in protecting group interests, the assessment of benefits and harms, and the protection of vulnerable participants.

## **PLoS Neglected Tropical Diseases**

October 2012

<http://www.plosntds.org/article/browseIssue.action>

[Reviewed earlier]

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

(Accessed 24 November 2012)

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

Biological Sciences - Population Biology:

### **Self-boosting vaccines and their implications for herd immunity**

Nimalan Arinaminpathy, Jennie S. Lavine, and Bryan T. Grenfell

PNAS 2012 ; published ahead of print November 19, 2012, doi:10.1073/pnas.1209683109

#### *Abstract*

Advances in vaccine technology over the past two centuries have facilitated far-reaching impact in the control of many infections, and today's emerging vaccines could likewise open new opportunities in the control of several diseases. Here we consider the potential, population-level effects of a particular class of emerging vaccines that use specific viral vectors to establish long-term, intermittent antigen presentation within a vaccinated host: in essence, "self-boosting" vaccines. In particular, we use mathematical models to explore the potential role of such vaccines in situations where current immunization raises only relatively short-lived protection. Vaccination programs in such cases are generally limited in their ability to raise lasting herd

immunity. Moreover, in certain cases mass vaccination can have the counterproductive effect of allowing an increase in severe disease, through reducing opportunities for immunity to be boosted through natural exposure to infection. Such dynamics have been proposed, for example, in relation to pertussis and varicella-zoster virus. In this context we show how self-boosting vaccines could open qualitatively new opportunities, for example by broadening the effective duration of herd immunity that can be achieved with currently used immunogens. At intermediate rates of self-boosting, these vaccines also alleviate the potential counterproductive effects of mass vaccination, through compensating for losses in natural boosting. Importantly, however, we also show how sufficiently high boosting rates may introduce a new regime of unintended consequences, wherein the unvaccinated bear an increased disease burden. Finally, we discuss important caveats and data needs arising from this work.

### **Public Health Ethics**

Volume 5 Issue 2 July 2012

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

[Reviewed earlier]

### **Trends in Molecular Medicine**

Volume 18, Issue 11, Pages 627-688 (November 2012)

<http://www.sciencedirect.com/science/journal/14714914>

[Reviewed earlier; No relevant content]

### **Science**

23 November 2012 vol 338, issue 6110, pages 1001-1116

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

[No relevant content]

### **Science Translational Medicine**

21 November 2012 vol 4, issue 161

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

[No relevant content]

### **Vaccine**

Volume 30, Issue 50, Pages 7131-7342 (26 November 2012)

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

#### ***Meeting Report***

**[Translating vaccine policy into action: A report from the Bill & Melinda Gates Foundation Consultation on the prevention of maternal and early infant influenza in resource-limited settings](#)**

Pages 7134-7140

Justin R. Ortiz, Kathleen M. Neuzil, Vincent I. Ahonkhaj, Bruce G. Gellin, David M. Salisbury, Jennifer S. Read, Richard A. Adegbola, Jon S. Abramson

*Abstract*

Immunization of pregnant women against influenza is a promising strategy to protect the mother, fetus, and young infant from influenza-related diseases. The burden of influenza during pregnancy, the vaccine immunogenicity during this period, and the robust influenza vaccine safety database underpin recommendations that all pregnant women receive the vaccine to decrease complications of influenza disease during their pregnancies. Recent data also support maternal immunization for the additional purpose of preventing disease in the infant during the first six months of life.

In April 2012, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization recommended revisions to the WHO position paper on influenza vaccines. For the first time, SAGE recommended pregnant women should be made the highest priority for inactivated seasonal influenza vaccination. However, the variable maternal influenza vaccination coverage in countries with pre-existing maternal influenza vaccine recommendations underscores the need to understand and to address the discrepancy between recommendations and implementation success.

We present the outcome of a multi-stakeholder expert consultation on inactivated influenza vaccination in pregnancy. The creation and implementation of vaccine policies and regulations require substantial resources and capacity. As with all public health interventions, the existence of perceived and real risks of vaccination will necessitate effective and transparent risk communication. Potential risk allocation and sharing mechanisms should be addressed by governments, vaccine manufacturers, and other stakeholders. In resource-limited settings, vaccine-related issues concerning supply, formulation, regulation, evidence evaluation, distribution, cost-utility, and post-marketing safety surveillance need to be addressed. Lessons can be learned from the Maternal and Neonatal Tetanus Elimination Initiative as well as efforts to increase vaccine coverage among pregnant women during the 2009 influenza pandemic. We conclude with an analysis of data gaps and necessary activities to facilitate implementation of maternal influenza immunization programs in resource-limited settings.

### **WHO Article**

### **[Monitoring of progress in the establishment and strengthening of national immunization technical advisory groups](#)**

Original Research Article

Pages 7147-7152

Philippe Duclos, Stephanie Ortynsky, Nihal Abeysinghe, Niyazi Cakmak, Cara Bess Janusz, Barbara Jauregui, Richard Mihigo, Liudmila Mosina, Nahad Sadr-Azodi, Yashohiro Takashima, Laure Dumolard, Marta Gacic-Dobo

### ***Abstract***

The majority of industrialized and some developing countries have established technical advisory bodies to guide and formulate national immunization policies and strategies. These are referred to as National Immunization Technical Advisory Groups (NITAGs), WHO and its partners have placed a high priority on assisting in the establishment or strengthening of functional, sustainable, and independent NITAGs. To enable systematic global monitoring of the existence and functionality of NITAGs, in 2010, WHO and UNICEF included related questions in the WHO–UNICEF Joint Reporting Form (JRF) that provides an official means for WHO and UNICEF to collect indicators of immunization programme performance.

This paper presents the status of NITAGs based on the analysis of the 2010 JRF. Although 115 countries (64% of responders) reported having a NITAG in 2010, only 50% of countries reported the existence of a NITAG with a formal administrative or legislative basis. Despite limitations in the ability to compare 2010 JRF data with that from a 2008 global survey, it appears that substantial progress has been achieved globally over with 43 committees reporting

affirmatively about six NITAG process indicators, compared with 23 in the 2008 survey. Impressive progress has been observed in the proportion of countries reporting NITAGs with formal terms of reference (24% increase), a legislative or administrative basis (10% increase), and a requirement for members to disclose their interests (14% increase). Some of the poorest developing countries now enjoy support from a NITAG which meet all six process indicators. These may serve as examples for other countries.

### **[The cost-effectiveness of a 13-valent pneumococcal conjugate vaccination for infants in England](#)**

Original Research Article

Pages 7205-7213

Albert Jan van Hoek, Yoon Hong Choi, Caroline Trotter, Elizabeth Miller, Mark Jit

#### *Abstract*

##### Background

In the immunisation schedule in England and Wales, the 7-valent pneumococcal conjugate vaccine (PCV-7) was replaced by the 13-valent vaccine (PCV-13) in April 2010 after having been used since September 2006. The introduction of PCV-7 was informed by a cost effectiveness analysis using an infectious disease model which projected herd immunity and serotype replacement effects based on the post-vaccine experience in the United States at that time.

##### Aim

To investigate the cost effectiveness of the introduction of PCV-13.

##### Method

Invasive disease incidence following vaccination was projected from a dynamic infectious disease model, and combined with serotype specific disease outcomes obtained from a large hospital dataset linked to laboratory confirmation of invasive pneumococcal disease. The economic impact of replacing PCV-7 with PCV-13 was compared to stopping the use of pneumococcal conjugate vaccination altogether.

##### Results

Discontinuing PCV-7 would lead to a projected increase in invasive pneumococcal disease, costs and loss of quality of life compared to the introduction of PCV-13. However under base case assumptions (assuming no impact on non-invasive disease, maximal competition between vaccine and non-vaccine types, time horizon of 30 years, vaccine price of £49.60 a dose + £7.50 administration costs and discounting of costs and benefits at 3.5%) the introduction of PCV-13 is only borderline cost effective compared to a scenario of discontinuing of PCV-7. The intervention becomes more cost-effective when projected impact of non-invasive disease is included or the discount factor for benefits is reduced to 1.5%.

##### Conclusion

To our knowledge this is the first evaluation of a transition from PCV-7 to PCV-13 based on a dynamic model. The cost-effectiveness of such a policy change depends on a number of crucial assumptions for which evidence is limited, particularly the impact of PCV-13 on non-invasive disease.

### **[Re-emergence of diphtheria and pertussis: Implications for Nigeria](#)**

Original Research Article

Pages 7221-7228

A.E. Sadoh, R.E. Oladokun

#### *Abstract*

In the prevaccine era pertussis and diphtheria were responsible for significant morbidity and mortality in children. In the United States of America more than 125,000 cases of diphtheria with 10,000 deaths were reported annually in the 1920s. In the same period about 1.7 million

cases of pertussis with 73,000 deaths were also reported. Vaccination against these two diseases has caused remarkable reduction in the morbidity and mortality from these diseases both in developed and developing countries. The initial vaccines were the combined diphtheria toxoid and whole cell pertussis vaccine.

The recent reported increases in the incidence of these two diseases in countries, which maintain high childhood vaccination coverage is a source of concern not only to these countries but also for developing countries with weak immunization programmes. Nigeria for example reported 11,281 cases of pertussis, the second highest number of cases worldwide in 2009. Waning immunity in adult and adolescent populations has been reported and epidemiologically, more cases are being reported in adults and adolescents. Also a high proportion of pertussis cases are being reported in infants and most of these infant cases are linked to adult/adolescent sources.

Recent approaches to control of these diseases include booster doses of combined diphtheria, tetanus and acellular pertussis vaccine while the cocooning strategy (which is immunizing every person who is likely to have contact with a given infant such as mother, father, grandparents and health care workers) is being used in a number of countries.

For developing countries including Nigeria where the capacity for making the diagnosis of both diseases is limited, strengthening of routine immunization as well as diagnostic capacity is imperative. Research to determine current levels of immunity in children, adolescents and adults is required. This will enable the determination of the need for booster doses and the age at which such boosters should be administered. Improved surveillance will be needed to delineate current epidemiological profiles of both diseases.

### **[Causality assessment of adverse events reported to the Vaccine Adverse Event Reporting System \(VAERS\)](#)**

Original Research Article

Pages 7253-7259

Anita M. Loughlin, Colin D. Marchant, William Adams, Elizabeth Barnett, Roger Baxter, Steve Black, Christine Casey, Cornelia Dekker, Katherine M. Edwards, Jerold Klein, Nicola P. Klein, Philip LaRussa, Robert Sparks, Kathleen Jakob

#### *Abstract*

Adverse events following immunization (AEFI) reported to the national Vaccine Adverse Event Reporting System (VAERS) represent true causally related events, as well as events that are temporally, but not necessarily causally related to vaccine.

#### Objective

We sought to determine if the causal relationships between the vaccine and the AEFI reported to VAERS could be assessed through expert review.

#### Design

A stratified random sample of 100 VAERS reports received in 2004 contained 13 fatal cases, 19 cases with non-fatal disabilities, 39 other serious non-fatal cases and 29 non-serious cases. Experts knowledgeable about vaccines and clinical outcomes, reviewed each VAERS report and available medical records.

#### Main outcome measures

Modified World Health Organization criteria were used to classify the causal relationship between vaccines and AEFI as definite, probable, possible, unlikely or unrelated. Five independent reviewers evaluated each report. If they did not reach a majority agreement on causality after initial review, the report was discussed on a telephone conference to achieve agreement.

#### Results

108 AEFIs were identified in the selected 100 VAERS reports. After initial review majority agreement was achieved for 83% of the AEFI and 17% required further discussion. In the end, only 3 (3%) of the AEFI were classified as definitely causally related to vaccine received. Of the remaining AEFI 22 (20%) were classified as probably and 22 (20%) were classified as possibly related to vaccine received; a majority (53%) were classified as either unlikely or unrelated to a vaccine received.

#### Conclusions

Using VAERS reports and additional documentation, causality could be assessed by expert review in the majority of VAERS reports. Assessment of VAERS reports identified that causality was thought to be probable or definite in less than one quarter of reports, and these were dominated by local reactions, allergic reactions, or symptoms known to be associated with the vaccine administered.

#### **[Cost-effectiveness of pertussis booster vaccination in the Netherlands](#)**

Original Research Article

Pages 7327-7331

Mark H. Rozenbaum, Elisabetta De Cao, Maarten J. Postma

#### *Abstract*

The aim of the current study is to estimate the epidemiological and economical consequences of several extended pertussis booster vaccination strategies and to explore the impact of parameters surrounded by large uncertainty on the cost-effectiveness.

We developed an age structured transmission dynamic model to evaluate the impact of programs targeting (i) adolescents or adults using a single booster dose, (ii) a combination of adolescent and adult vaccination, and (iii) an every 10 years booster dose.

The base case analysis, that is a single adolescent booster administered at the age of 12 years, resulted in a reduction of pertussis infections. However, due to an increase in the number of symptomatic infections in adults, the benefits in terms of QALYs gained and costs saved in children were partly offset. Despite these negative indirect effects in the adult population, administering an additional booster dose could still be considered cost effective with an ICER of €4200 per QALY gained. Combining an adolescent booster dose at the age of 10 (most cost-effective age for a single adolescent booster dose) with an adult (18–30 years) booster dose always resulted in favorable ICERs (<€10,000/QALY). Finally the every 10 year booster dose resulted in an ICER of €16,900 per QALY. The impact of different assumptions regarding the disease epidemiology, disease-related parameters, and vaccination program-related issues was limited.

To conclude, we show that extended pertussis booster vaccination strategies are likely to be considered as cost-effective.

#### **Vaccine: Development and Therapy**

(Accessed 24 November 2012)

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

[No new relevant content]

#### **Value in Health**

Vol 15 | No. 7 | November 2012

<http://www.valueinhealthjournal.com/current>

**ISPOR 15th Annual European Congress Research Abstracts**

[Reviewed earlier]

***From Google Scholar+: Dissertations, Theses, Selected Journal Articles***

**[Epidemiology of Invasive Pneumococcal Disease among High-Risk Adults since Introduction of Pneumococcal Conjugate Vaccine for Children](#)**

RD Muhammad, R Oza-Frank, E Zell, R Link-Gelles... - Clinical Infectious Diseases, 2012  
Background. Certain chronic diseases increase risk for invasive pneumococcal disease (IPD) and are indications for receipt of 23-valent pneumococcal polysaccharide vaccine (PPV23). Since the pediatric introduction of 7-valent pneumococcal conjugate vaccine ( ...

**American Journal of Preventive Medicine**

[Volume 43, Issue 6, Supplement 5](#), December 2012, Pages S490–S496

*Research Collaboration with 2-1-1 to Eliminate Health Disparities*

*2-1-1 research and program innovation*

**Human Papillomavirus Vaccine: 2-1-1 Helplines and Minority Parent Decision-Making**

Lara S. Savas, PhD, Maria E. Fernández, PhD, David Jobe, MSW, Chakema C. Carmack, PhD

*Abstract*

Background

Research is needed to understand parental factors influencing human papillomavirus (HPV) vaccination, particularly in groups with a higher burden of cervical cancer.

Purpose

To determine correlates of HPV vaccination among a sample of low-income parents of age-eligible daughters (aged 9–17 years) who called the 2-1-1 Helpline. Secondary analyses describe potential differences in HPV vaccination correlates by Hispanic and black parent groups, in particular.

Methods

This 2009 cross-sectional feasibility survey of cancer prevention needs was conducted in Houston at the 2-1-1 Texas/United Way Helpline. In 2012, to examine the association between parental psychosocial, cognitive, and decisional factors and HPV vaccination uptake (one or two doses), bivariate and multivariable logistic regression analyses were conducted for minority parents and for Hispanic and black parent groups, separately.

Results

Lower rates of HPV vaccination uptake were reported among minority daughters of 2-1-1 callers (29% overall) compared with national and Texas rates. In final adjusted analysis, factors positively associated with HPV vaccination uptake included being offered the vaccination by a doctor or nurse, belief that the vaccine would prevent cervical cancer, and Hispanic ethnicity. Secondary analyses detected differences in factors associated with vaccination in Hispanic and black groups.

Conclusions

Findings indicate low levels of vaccination among 2-1-1 callers. Increased understanding of determinants of HPV vaccination in low-income minority groups can guide interventions to increase coverage. Because 2-1-1 informational and referral services networks reach populations considered medically underserved, 2-1-1 can serve as a community hub for informing development of and implementing approaches aimed at hard-to-reach groups.

### **Accelerating the development of a therapeutic vaccine for human Chagas disease: rationale and prospects**

E Dumonteil, ME Bottazzi, B Zhan, MJ Heffernan... - Expert Review of Vaccines, 2012  
Chagas disease is a leading cause of heart disease affecting approximately 10 million people in Latin America and elsewhere worldwide. The two major drugs available for the treatment of Chagas disease have limited efficacy in *Trypanosoma cruzi*-infected adults ...

### **Science denial: a guide for scientists**

J Rosenau - Trends in Microbiology, 2012  
... You do not expect to see Draco Malfoy carrying a Hermione Granger poster, let alone one in which she touts the whooping cough vaccine. Yet at the ... scientific consensus. The vaccine drive at Dragon\*Con fits this model beautifully. The ...

### **Interview: Future of immunotherapy for colorectal cancer**

J Marshall - Colorectal Cancer, 2012  
... maintaining his regular clinical practice. His own research focuses on the development of a novel vaccine for the treatment of advanced colon cancer. Q What led you to focus your research on immunotherapy in colorectal cancer? ...

### ***Media Watch***

Beginning in June 2012, *Vaccines: The Week in Review* expanded 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 of 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.

### **BBC**

<http://www.bbc.co.uk/>

Accessed 24 November 2012

[No new, unique, relevant content]

### **Economist**

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

Accessed 24 November 2012

[No new unique, relevant content]

### **Financial Times**

<http://www.ft.com>

*Accessed 24 November 2012*  
[No new unique, relevant content]

### **Forbes**

<http://www.forbes.com/>  
*Accessed 24 November 2012*  
[No new unique, relevant content]

### **Foreign Affairs**

<http://www.foreignaffairs.com/>  
November/December 2012 Volume 91, Number 6  
*Accessed 24 November 2012*  
[No new unique, relevant content]

### **Foreign Policy**

<http://www.foreignpolicy.com/>  
*Accessed 24 November 2012*  
[No new unique, relevant content]

### **The Guardian**

<http://www.guardiannews.com/>  
*Accessed 24 November 2012*  
[No new, unique, relevant content]

### **The Huffington Post**

<http://www.huffingtonpost.com/>  
Accessed 24 November 2012  
[No new, unique, relevant content]

### **New Yorker**

<http://www.newyorker.com/>  
*Accessed 24 November 2012*  
[No new, unique, relevant content]

### **NPR/National Public Radio [U.S.]**

***Public Health***  
*Accessed 24 November 2012*  
[No new, unique, relevant content]

### **New York Times**

<http://www.nytimes.com/>  
Accessed 24 November 2012.  
[No new, unique, relevant content]

### **Reuters**

<http://www.reuters.com/>  
*Accessed 24 November 2012*

**Nurses can help improve vaccination rates: study**

By Genevra Pittman

NEW YORK | Fri Nov 23, 2012 9:58am EST

Excerpt

(Reuters Health) - More elderly and at-risk adults get their flu and pneumonia vaccinations when the shots are coordinated and given by nurses instead of doctors, a new analysis suggests.

Researchers linked the changeover to a 44-percent increase in patients' chances of getting a flu shot and a more than doubling of their likelihood of getting vaccinated against pneumonia. Jeffrey Johnson, who worked on the study, said there's been a recent effort to get public health nurses and pharmacists involved in giving vaccines - although policies vary by state in the U.S. He said shifting responsibility to non-doctors might be especially helpful for people with chronic diseases.

"The family physician has all of the responsibility to look after the patient, and so somebody with diabetes, for example, comes in and their first concern is their blood sugar and their blood pressure and pretty soon, the time for the visit is up," Johnson, from the University of Alberta in Edmonton, Canada, told Reuters Health...

<http://www.reuters.com/article/2012/11/23/us-nurses-vaccination-idUSBRE8AM0IK20121123>

### **Wall Street Journal**

<http://online.wsj.com/home-page>

*Accessed 24 November 2012*

[No new, unique, relevant content]

### **Washington Post**

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

*Accessed 24 November 2012*

[No new, unique, relevant content]

### ***Twitter Watch*** [accessed 24 November 2012 - 09:14]

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.

#### **GAVI Alliance @GAVIAlliance**

T-12: Over 500 global health and government leaders will gather [#GAVIpartners](#) Forum in Dar Es SDalam, Tanzania. <http://ht.ly/fw9fW>

3:09 AM - 23 Nov 12

#### **Seth Berkley @GAVISeth**

Despite good vax for A, C, Y, W135 mening meningitis, type B still cause morb/mort. New Grp B vax received EU approval <http://reut.rs/QxfsT2>

1:16 AM - 23 Nov 12

#### **Peter Singer @PeterASinger**

Inspired: Canada funds 68 bold, inventive ways to improve health, save lives in developing countries: <http://bit.ly/ScDLnp> [@globalhealth](#)

Retweeted by [Global Health](#)

7:54 AM - 22 Nov 12

[The Global Fund @globalfundnews](#)

News Flash Special: Interview with Mark Dybul <http://tinyurl.com/d9lv2e3>

3:03 AM - 21 Nov 12

[PAHO/WHO @pahowho](#)

Delegates from 76 countries launch Global Mechanism in Buenos Aires to fight Drug

Counterfeiting cc: [@who](#) [http://new.paho.org/hq/index.php?option=com\\_content&view=article&id=7484%3Adelegados-de-76-paises-ponen-en-marcha-en-buenos-aires-mecanismo-mundial-contra-la-falsificacion-de-medicamentos&catid=740%3Anews-press-releases&Itemid=1926&lang=en&Itemid=1926](http://new.paho.org/hq/index.php?option=com_content&view=article&id=7484%3Adelegados-de-76-paises-ponen-en-marcha-en-buenos-aires-mecanismo-mundial-contra-la-falsificacion-de-medicamentos&catid=740%3Anews-press-releases&Itemid=1926&lang=en&Itemid=1926) ...

5:41 PM - 20 Nov 12

\* \* \* \*

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